THE FLORIDA BAR
Health Law Section Newsletter
THE RESOURCE FOR FLORIDA HEALTH LAW
The Florida Bar Health Law Section
Vol. XVII, No. 11 www.flabarhls.org Spring 2017

INSIDE:

The False Claims Act
The Troll Under Healthcare's Bridge[1]

By David B. Honig[2]

On December 14, 2016, the United States Department of Justice announced the recovery of more than $4.7 billion in False Claims Act (FCA) settlements and judgments. It was the third-highest total in history, and more than $2.5 billion came from the healthcare industry.

Only a small percentage of the recoveries came from jury verdicts. Most of the money recovered came from settlement agreements, usually without findings of wrongdoing, from doctors, hospitals, drug manufacturers, and others confronted with the enormous risks inherent in FCA litigation and resolving the case for a small percentage of that risk.

The year 2016 was pivotal for the FCA. It was the year of a tremendously important Supreme Court decision that could expose healthcare providers to whole new areas of FCA liability based upon state and federal regulations. Penalties more than doubled to a minimum just over $11,000 per claim and a maximum just over $22,000 per claim, massively increasing both the risk of litigation and the likelihood of settling FCA cases even in the absence of wrongdoing. And it saw a new focus on the investigation and even the criminal indictment of individuals involved with entities sued under the FCA.

The Caldwell Announcement and Yates Memo

On September 17, 2014, Leslie R. Caldwell, Assistant Attorney General for the Criminal Division of the United States Department of Justice, appeared at the Taxpayers Against Fraud Education Fund Conference. At that conference, she made an announcement that rippled through the (FCA) world and that directly affected how the government reviews *qui tam* cases against healthcare providers.[3] Ms. Caldwell announced the commitment of significant new resources to DOJ's Criminal Division for investigating FCA cases.

Ms. Caldwell announced a new process for the review of *qui tam* cases. All new cases, regardless of the allegations, would be shared with the Criminal Division upon filing for review by Fraud Section prosecutors. If the prosecutors identified a potential criminal case they would investigate the allegations with support from "the FBI, HHS-OIG, the Postal Inspection Service and numerous other law enforcement agencies."[4]

For healthcare providers, this means that any FCA accusations against them, no matter how frivolous, places them under the microscope of the DOJ's Criminal Division.

On September 9, 2015, Sally Quillian Yates, former Deputy Attorney General, released a DOJ memorandum: *the Yates Memo*. Titled, *Individual Accountability for Corporate Wrongdoing*, the Memo directly targeted individuals:

> One of the most effective ways to combat corporate misconduct is by seeking accountability from the individuals who perpetrated the wrongdoing.[5]

Ms. Yates laid out the DOJ's plan to "fully leverage its resources to identify culpable individuals at all levels in corporate cases"[6] in both civil and criminal matters.

The Yates Memo set out six steps the government would take to target individuals. To receive

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Provider Beware: MACRA Implementation Fraught with Fraud and Abuse Implications

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Although the fate of the Center for Medicare and Medicaid Innovation (CMMI) and the mandatory alternative payment models thereunder face threat of repeal under Republican leadership, the *Medicare Access and Chip Reauthorization Act* (MACRA) passed with overwhelming bipartisan support (passed the U.S. House 392-37; passed the U.S. Senate 92-8), signaling that both Republicans and Democrats back the shift to value-based reimbursement.[2]

MACRA, which took effect January 1 of this year, sends a dramatic signal that providers must embrace the new value-based paradigm. Like other value-based initiatives, MACRA requires that providers incur financial risk for clinical outcomes and cost of care.

As participating-providers brace for MACRA's operational impact, healthcare counsel must brace for the legal implications of the legislation. Depending on the specific facts and circumstances, value-based payment models including those utilized by physicians to meet MACRA standards, may implicate federal fraud and abuse laws.

MACRA Overview

Eligible providers participate in MACRA through one of two tracks: (i) the new Merit-Based Incentive Payment System (MIPS) under which they receive payment rate increases or cuts based on their ability to meet standards; or (ii) the Advanced Alternative Payment Models (APMs) track, under which they receive bonuses for incurring substantial financial risk in qualifying APMs.

Either track requires providers to assume financial accountability for the health of patients beyond a single outpatient procedure, office visit or inpatient admission. Thus, formerly independent providers are incentivized to coordinate care with one another in order to align patient care plans and transitions of care.

Logically, providers and health administrators look to financially incentivize providers for care coordination efforts. However, creating financial incentive models amongst otherwise autonomous providers is a legal hotbed as the Stark Law, Anti-Kickback Statute and Civil Monetary Penalty laws (collectively, "Fraud and Abuse Laws") treat such shared financial incentives as suspect.

Civil Monetary Penalty Law (CMP)

Congress anticipated such conflicts with CMP. Prior to MACRA, CMP prohibited a hospital from knowingly making a payment directly or indirectly to a physician as an inducement to reduce or limit any services to Medicare or Medicaid beneficiaries under the physician's care.[3]

As MACRA necessarily induces physicians to limit unnecessary services to Medicare beneficiaries, §512(a) of MACRA amends §§1128A(b)(1) and (2) of the *Civil Monetary Penalty Law* to prohibit hospitals from knowingly making a payment directly or indirectly to a physician as an inducement to refer or limit medically necessary services to Medicare or Medicaid beneficiaries under a physician's care.

However, MACRA has not altered the Anti-Kickback Statute or Stark Law. Thus, MACRA incentive programs must meet a safe harbor under the Anti-Kickback Statute and an exception of Stark Law to comply with the law.

The Anti-Kickback Statute

Under the Anti-Kickback Statute (AKS), it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services payable by a Federal health care program.[4] Pursuant to AKS, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.[5]

Courts have held that AKS covers any arrangement under which one purpose of the remuneration is to obtain money for the referral of services or to induce further referrals. Thus, financial incentives shared amongst referring providers may be viewed as an inducement for referrals. For example, MACRA compensation arrangements that distribute cost savings generated by referrals to providers with proven cost-efficient services may implicate AKS.

Although 42 C.F.R. §1001.952 provides safe harbors for various payment and business practices, no safe harbor specifically exempts cost-saving financial incentive programs tied to MACRA or alternative payment model implementation. Similarly, the OIG has issued a number of Advisory Opinions approving gainsharing arrangements; however, each Advisory Opinion is limited to the specific set of circumstances presented, and protects only the hospital or provider making the request.[6] Although the OIG Advisory Process is available to any provider, it is an arduous, expensive process that may take years to complete.

The Stark Law presents similar barriers to MACRA compensation arrangements.

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This newsletter is prepared and published by the Health Law Section of The Florida Bar.

The Physician Self-Referral Law (Stark Law)

Stark is a strict liability statute, meaning proof of specific intent to violate the law is not required. The Stark law prohibits a physician from making referrals for "designated health services" (DHS) to an entity with which he or she (or an immediate family member) has a financial relationship (including compensation or ownership) that are payable by Medicare; and prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for DHS furnished as a result of a prohibited referral.[7] If a financial relationship exists between a physician and a DHS entity, in order for a physician to refer to the DHS entity and for such entity to bill for the service, an applicable exception must be met.

The Stark Law grants the Secretary of HHS the authority to create regulatory exceptions for financial relationships that "pose no risk of program or patient abuse."[8] Despite HHS' authority to establish such exceptions for incentive compensation arrangements under MACRA, no such exception exists. HHS has argued that providing such an exception "[w]ould not provide sufficient flexibility for innovative, effective gainsharing and incentive compensation programs."[9] The agency added that "[t]he variety and complexity of gainsharing and similar arrangements would make it difficult to craft a "one-size-fits-all" set of conditions that are sufficiently "bright line" to facilitate compliance and enforceability, yet sufficiently flexible to permit innovation without any risk of program or patient abuse."[10]

Thus, MACRA compensation arrangements must fit into an existing Stark exception, many of which require that the volume or value of a physician's referrals or other business generated between the parties must not be a consideration when determining physician compensation. Thus, Stark Law presents a particularly difficult obstacle to structuring effective value-based payment programs that necessarily take into consideration the "value" of referrals.

HHS recently admitted the difficulty of structuring MACRA compensation arrangemetns to comply with Stark Law stating to Congress that "[e]xisting exceptions to the physician self-referral law, while useful, may not be sufficiently flexible to encourage a variety of non-abusive and beneficial gainsharing, P4P [pay for performance], and similar arrangements."[11]

HHS added that the prohibition on considering "volume or value" of referrals when formulating physician compensation "can pose impediments for the implementation of gainsharing arrangements, because compensation paid to a physician for reducing costs or increasing profits through changes to his or her patient care practice could be interpreted to take into account the volume or value of the physician's referrals of DHS for Medicare beneficiaries."[12]

Waivers for Medicare Shared Savings Program and Center for Medicare and Medicaid Innovation Initiatives

Recognizing the barriers that AKS and Stark Law pose to implementation of value based payment models, HHS has issued certain waivers of the physician self-referral law and AKS to allow gainsharing and similar arrangements in connection with certain APMs, including an "ACO pre-participation waiver", and an "ACO participation waiver."[13]

Fraud and Abuse waivers issued to date are available at: https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html and on the OIG's website.

However, such waivers are only applicable to specific alternative payment and care delivery models, such as the MSSP and bundled payment programs. Although such waivers are essential for facilitating these programs, the program-by-program waiver approach may not provide sufficient protection from the overall vulnerability of the implication of Fraud and Abuse Laws.

The American Hospital Association and other provider association groups continue to advocate for HHS to grant broad waivers of Fraud and Abuse Laws for new payment models necessary for MACRA implementation. The American Hospital Association recently wrote, "[t]he fraud and abuse laws need to be adapted to support not hamper the new payment models. To that end, Congress should create legal safe zones to support and foster arrangements designed to achieve the goals of payment-for-value rather than volume-based programs…. There should be clear and comprehensive protection for arrangements designed and implemented to meet those goals."[14]

Conclusion

For now, when advising clients on value based payment initiatives, including MACRA, it is best to ensure arrangements are properly structured to satisfy the requirements of an applicable exception to the physician self-referral law and not violate the Federal Anti-Kickback statute. All provider clients should be warned of the Fraud and Abuse implications of the value-based reimbursement paradigm.

Endnotes

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2 *Medicare Access and CHIP Reauthorization Act of 2015,* H.R. 2, Pub. L. 114-10; 129 Stat. 100 (2015).

3 42 U.S.C. § 1320a.

4 42 U.S.C. § 1320a-7b.

5 *Id.*

6 *See* OIG Advisory Opinions 01-01, 05-02, 05-03, 05-04, 05-05, 05-06, 06-22, 07-21, 07-22, 08-09, 08-15, 08-21, and 09-06.

7 42 U.S.C. § 1395nn.

8 *Id.*

9 73 Fed. Reg. 69726, 69793-79794 (Nov. 19, 2008).

10 73 Fed. Reg. 38548.

11 Report to Congress titled "Fraud and Abuse Laws Regarding Gainsharing or Similar Arrangements between Physicians and Hospitals as Required by Section 512(b) of the Medicare Access and CHIP reauthorization Act of 2015," https://www.cms.gov/Medicare/Fraud-and-Abuse/.../Report-to-Congress-2015.pdf.

12 *Id.*

13 76 Fed. Reg.67992 and 80 Fed. Reg. 66726.

14 "Legal (Fraud and Abuse) Barriers to Care Transformation and How to Address Them (2016), www.aha.org/content/16/barrierstocare-full.pdf.

The Discoverability of Physician Peer Review and Disciplinary Records Under State and Federal Law in Florida State and Federal Courts

Stephen P. Smith[1]

I. Introduction

A contentious discovery issue in litigation involving termination, revocation or suspension of a physician's clinical privileges to practice medicine at a hospital is whether the physician plaintiff is entitled to obtain peer review and disciplinary materials concerning other physicians in the course of such proceedings. The treatment of this issue depends entirely on whether the case is in state or federal court. In Florida state courts, the materials are immune from discovery pursuant to Fla. Stat. § 395.0193(8).[2]

This is not the case in federal court, however. Federal common law provides that no medical peer review discovery privilege applies in such discrimination or civil rights cases in federal court. The Eleventh Circuit Court of Appeals has specifically rejected the idea of any such medical peer review privilege in cases in federal court, no matter what the relevant state statute provides.

This can lead to bizarre results. For example, non-party physician disciplinary and peer review materials might be protected from disclosure in a Florida state court case involving Florida residents claims under the Florida Civil Rights Act ("FCRA"), which has the same elements as claims under Title VII to the Civil Rights Act of 1964 ("Title VII") or 42 U.S.C. § 1981 ("Section 1981"). Nevertheless, in an identical case filed in federal court involving federal claims, the same materials would not be protected from disclosure simply by virtue of the presence of diverse defendants or the assertion of federal civil rights claims by the plaintiff physician.

II. The Ability to Discover Physician Peer Review and Disciplinary Materials Under State Law in Florida

Florida state law provides that physician peer review materials are immune from discovery in civil litigation:

> The investigations, proceedings, and records of the board, or agent thereof with whom there is a specific written contract for the purposes of this section, as described in this section shall not be subject to discovery or introduction into evidence in any civil action against a provider of professional health services arising out of matters which are the subject of evaluation and review by such board, and no person who was in attendance at a meeting of such board or its agent shall be permitted or required to testify in any such civil action as to any evidence or other matters produced or presented during the proceedings of such board or its agent or as to any findings, recommendations, evaluations, opinions, or other actions of such board or its agent or any members thereof.[3]

Section 395.0193, Florida Statutes, provides a similar protection with respect to hospital peer review committees.[4] This privilege has been strictly construed by Florida state courts, including the Florida Supreme Court.[5] The privilege has been strictly enforced, even though Florida courts have recognized that to do so impinges on the rights of some physician plaintiffs to discover information or documents that might be essential to prove their claims.[6] This statutory protection has even been upheld in cases involving the discovery of physician peer review records from non-parties.[7]

III. The Ability to Discover Physician Peer Review and Disciplinary Materials Under Federal Law in Florida

A. The Eleventh Circuit's Take on the Issue

In *Adkins v. Christie*, the Eleventh Circuit addressed the applicability of a state medical peer review privilege in civil rights cases in federal court and concluded the privilege did not apply.[8] In *Adkins*, an African American surgeon alleged that hospital administrators and physicians who served on a Georgia hospital's medical executive committee violated his civil rights in summarily suspending and not renewing his privileges at the hospital based on his race.[9] In discovery, the physician requested copies of the peer review records of every physician at the hospital during his seven years at the hospital.[10] The defendants filed a motion for protective order premised upon Georgia's state medical peer review privilege.[11]

The federal district court concluded Georgia's state statutory protection protected the requested non-party physician peer review materials from discovery, even in federal court.[12,13] On appeal, the Eleventh Circuit vacated the district court's grant of summary judgment to the defendant hospital administrators and medical executive committee members, finding the district court improperly limited the scope of discovery by allowing the plaintiff physician to obtain copies of peer review materials for only physicians in the hospital's Department of Surgery.[14] The Eleventh Circuit noted that, although all fifty states and the District of Columbia recognize some form of medical peer review privilege, both the federal Fourth and Seventh Circuit Courts of Appeal had previously determined there was no such corresponding federal privilege.[15] While acknowledging a federal medical peer review privilege would "promote vigorous oversight of physician performance," the *Adkins* court noted such a privilege "must be considered against a corresponding and overriding goal-the discovery of evidence essential to determining whether there has been discrimination in employment."[16] Also recognizing health care providers "have a legitimate interest in keeping peer review documents confidential and in protecting them from widespread dissemination," the *Adkins* court noted there is a difference between recognizing the privilege and protecting the confidentiality of such documents through protective orders or other mechanisms.[17]

B. Federal District Courts in Florida Also Have Not Recognized a Medical Peer Review Privilege.

Federal district courts in Florida have followed the *Adkins* decision faithfully.[18] Other district courts in the Eleventh

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Circuit have taken the same approach.[19]

IV. Discussion: The Privileged Nature of a Non-Party Physician's Peer Review and Disciplinary Records Depends on the Plaintiffs' Choice of Forum, The Citizenship of the Parties, and the Plaintiff's Choice as to Whether to Pursue Federal and State Law Claims or Just State Law Claims, Which Can Lead to Inconsistent Results

The crux issue with respect to whether to recognize a federal medical peer review privilege in discrimination cases brought by physicians against hospitals is, in the words of the federal Fourth Circuit of Appeal, "whether the interest in promoting candor in medical peer review proceedings outweighs the need for probative evidence in a discrimination case."[20] State and federal courts in Florida have chosen different paths in recognizing a medical peer review privilege in discovery in civil litigation. Nevertheless, this disparity in treatment between federal and state court can lead to truly bizarre results, with such materials protected in one forum (state court) but not the other (federal court).

Whether a non-party physicians' peer review and disciplinary materials are privileged or not in civil litigation thus currently depends entirely on the parties' choice of forum: state or federal court. This leads to inconsistent application of the privilege depending on whether the defendants are diverse or not, whether a plaintiff chooses to file an action in federal court if he is pursuing a federal claim, even if the plaintiff pursues state or federal claims that in some cases may be subject to identical legal standards, like Title VII and FCRA discrimination claims.

To make matters even worse, even for cases that were filed or removed to federal court, the materials could possibly receive different treatment depending on the basis for the federal court's jurisdiction. To the extent the case is in federal court under federal question jurisdiction, the materials would not be privileged from disclosure pursuant to any state statute protecting such materials from disclosure in discovery. The same would be true if all defendant(s) were diverse, thus making the basis for the court's jurisdiction diversity jurisdiction.[21] However, pursuant to Fed. R. Evid. 501, a state medical peer review privilege *may* apply if the basis for the federal court's jurisdiction is diversity but the plaintiff is pursuing *only* state law discrimination claims.

Similarly, if a plaintiff files suit in state court against a non-diverse defendant and asserts federal claims but the defendant(s) choose not to remove the case to federal court on the basis of federal question jurisdiction, then the plaintiff cannot obtain other physicians' peer review materials. What this means is that to some degree whether the non-party physicians' peer review and disciplinary records are privileged is up to the parties and, in particular, the plaintiff.

As noted by the federal Fifth Circuit Court of Appeals, "medical peer review materials are sensitive and inherently confidential, and protecting that confidentiality serves an important public interest."[22] Therefore, the only way to truly harmonize the differing treatment of physician peer review records under state and federal law in Florida would be to require a protective order or similar protection from disclosure before the records are produced in discovery in federal court. This also would safeguard the non-party physicians' privacy rights in their own peer review and disciplinary materials while also permitting the physician plaintiff to prove his or her claims. This would ensure, in the words of the *Adkins* court, the confidentiality of these records is not "compromised by wayward hands."[23]

Endnotes

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2 Physician peer review materials can include both peer review materials themselves, as well as testimony regarding or which takes place either during or in furtherance of the peer review process. This article will concentrate on the actual documentary materials themselves, as those are typically the most important in the types of civil rights/discrimination claims which physicians bring against hospitals at which their clinical privileges to treat patients are suspended or terminated or the physician is disciplined in some way.

3 Fla. Stat. § 395.0191(8).

4 Fla. Stat. § 395.0193(8).

5 *See*, *e.g.*, *Cruger v. Love*, 599 So. 2d 111, 114 (Fla.1992) (acknowledging the discovery privilege for peer review committees is "designed to provide that degree of confidentiality necessary for the full, frank medical peer evaluation which the legislature [has] sought to encourage.'") (quoting *Holly v. Auld*, 450 So.2d 217, 219-20 (Fla. 1984)); *Tenet Healthsystem Hosps., Inc. v. Taitel*, 855 So. 2d 1257, 1258 (Fla. 4th DCA 2003) (same); *Beverly Enters.-Fla., Inc. v. Ives*, 832 So. 2d 161 (Fla. 5th DCA 2002) (same); *Leikensohn v. Cornwell*, 434 So. 2d 1030 (Fla. 2d DCA 1983); *Fidelity & Cas. Co. of N.Y. v. Lopez*, 375 So. 2d 59 (Fla. 4th DCA 1979); *Argonaut Ins. Co. v. Peralta*, 358 So. 2d 232 (Fla. 3d DCA 1978).

6 *See Holly*, 450 So. 2d at 220.

7 *See*, *e.g.*, *Miami Heart Institute v. Reis*, 638 So. 2d 530 (Fla. 3d DCA 1994) (Florida medical peer review privilege protected from disclosure in physician's defamation action against medical center and administrators records relating to physician's application for staff privileges at a non-party heart institute even though medical center and administrators asserted need for records to prove their defenses.).

8 488 F.3d 1324 (11th Cir. 2007).

9 *Id.* at 1326-27.

10 *Id.* at 1327.

11 *Id.*

12 The case, which involved all non-diverse defendants, was in federal court pursuant to federal question jurisdiction based on the plaintiff's federal civil rights claims.

13 *Id.*

14 *Id.* at 1330-31.

15 *Id.* at 1327-28; *see also Virmani v. Novant Health Inc.*, 259 F.3d 284 (4th Cir. 2001); *Memorial Hosp. for McHenry County v. Shadur*, 664 F.2d 1058 (7th Cir. 1981).

16 *Id.* at 1328-29.

17 *Id.* ("In the absence of the privilege, the district court retains its authority to protect [a hospital's] interests through other established means such as protective orders, confidentiality agreements, and, when appropriate, by disclosure only after an in-camera review of these documents.").

18 *Awwad v. Largo Med. Ctr., Inc.*, No. 8:11-CV-1638-T-24TBM, 2012 WL 1231982, at *2 (M.D. Fla. Apr. 12, 2012) (ordering production of non-party physicians' peer review materials disciplined for the same offenses as the plaintiff).

19 *See, e.g., Mawulawde v. Board of Regents of University System of Georgia*, No. CV 105-099, 2007 WL 2460774, at *11 n.12 (S.D. Ga. Aug. 24, 2007) (ordering production of the physician plaintiff's comparator physicians' credentialing and disciplinary files but ordering the parties first to submit a consent protective order).

20 *Virmani v. Novant Health Inc.*, 259 F.3d 284, 287 (4th Cir. 2001).

21 This assumes, of course, that all defendants are diverse. As a matter of diversity jurisdiction, a defendant can remove a case from state to federal court only if *all* defendants in the action are not citizens of the state in which the lawsuit was filed, failing which the action cannot be removed to federal court.

22 *United States v. Harris Methodist Fort Worth*, 970 F.2d 94, 103 (5th Cir. 1992).

23 488 F.3d at 1329.

HIPAA & Cloud Computing

By Cathrine A. Hunter, Esq.[1],Woodward, Pires & Lombardo, P.A.

The Office of Civil Rights (OCR), operating under the U.S. Department of Health & Human Services, released guidance[2] on October 7, 2016 (herein after referred to as the "Guidance"), regulating the use of cloud computing. This Guidance was issued to assist covered entities, business associates, and cloud service providers (hereinafter referred to as "CSP" or "CPSs") in understanding, implementing, and fulfilling their responsibilities under the Health Information Portability and Accountability Act (hereinafter referred to as "HIPAA" or "HIPAA Rules").

For purposes of HIPAA, a covered entity is defined as a health plan, a health care clearinghouse, or a health care provider who conducts certain billing and payment related transactions electronically.[3] A business associate is defined as an entity or person, other than a member of the covered entity, that performs functions or activities on behalf of, or provides certain services to, the covered entity that involve creating, receiving, maintaining, or transmitting protected health information (PHI).[4]

When a covered entity engages the services of a CSP to create, receive, maintain, or transmit electronic protected health information (ePHI) on its behalf, such CSP is considered a business associate of the covered entity under HIPAA. Further, when a business associate subcontracts with a CSP to create, receive, maintain, or transmit ePHI on its behalf, the CSP subcontractor is also considered a business associate of the covered entity under HIPAA. Regardless of designation as a CSP, business associate, or subcontractor, compliance with the HIPAA Rules is mandatory in order to avoid enforcement fines by the OCR (fines for non-compliance can rise to $1.5 million per HIPAA violation).

Can a covered entity (or its business associate) utilize a CSP to store or process electronic protected health information?

Yes, a HIPAA covered entity or business associate may use the services of a CSP to create, receive, maintain, or transmit ePHI so long as the covered entity or business associate enters into a HIPAA-compliant business associate agreement[5] with said CSP. The basis of a business associate agreement is to identify and stipulate the permitted uses of ePHI by and between the business associate and CSP. In addition, the CSP is liable for meeting the requirements of the HIPAA Rules in addition to the terms of the business associate agreement between the parties.

Covered entities and business associates must also evaluate and conduct their own risk analysis of the CSP to identify and assess potential threats and vulnerabilities. These risk analyses are then used to establish safeguards for purposes of the business associate agreement. Be aware that the use of various cloud-based services (public, private, hybrid, etc.) can affect the level of exposure of potential threats and vulnerabilities.

Can a covered entity (or its business associate) use a CSP that stores electronic protected health information on servers outside of the United States?

While a majority of CSPs store ePHI within the United States, there are some that store ePHI on servers internationally. The HIPAA Rules allow for covered entities (or its business associates) to utilize a CSP who outsources the services and/or storage of ePHI on servers outside of the United States.[6] However, the use of these CSPs may create a greater margin of risks and vulnerabilities to the ePHI. In the event of a breach of the HIPAA Rules, the enforcement of those protections, as well as the sanctions of such breach, can present its own challenges in a foreign country. For example, if ePHI is stored on a server in a country where hacking, malware or other attacks are known to originate, it is the covered entity's (or its business associate's) responsibility to research and consider the risk of exposure, as well as the CSP's plans for safeguards for protection against a potential breach.

Does the Office for Civil Rights have a list of recommended HIPAA-compliant cloud services?

While the OCR does not endorse, certify, or recommend any specific HIPAA-compliant cloud service, it is highly advised that each covered entity (and business associate) conduct its own research to determine the right CSP to fit their needs and that comply with the HIPAA requirements. The OCR also encourages any covered entity or business associate to further its research on the various types of cloud computing through the National Institute of Standards and Technology.[7]

Is a CSP considered a business associate if it only stores encrypted electronic protected health information and does not have access to a decryption key?

When a covered entity employs a CSP, the CSP is considered a business associate of the covered entity under the HIPAA Rules, regardless if the CSP cannot view or access the ePHI.[8] A CSP

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is also considered to be a business associate even when the CSP handles encrypted ePHI and does not have a decryption key.[9]

Encryption can significantly reduce the risk of unauthorized access to ePHI. However, pursuant to the HIPAA Security Rule, encryption alone does not provide for safeguards to maintain the confidentiality, integrity, and availability of ePHI as required. For example, encryption alone cannot ensure the safeguarding against issues such as malware corruption. That withstanding, under the HIPAA Security Rule, a CSP in its role as a business associate, is responsible for implementing additional controls to eliminate unauthorized access to ePHI. For example, a customer of a CSP may have its own controls in place and the CSP may still require additional internal controls to authenticate a user's access. Both the covered entity (or its business associate) and CSP must confirm in writing, either in their business associate agreement or separate document, how each party will address these requirements. In the event of a security breach where the customer fails to implement and enforce certain security features pursuant to the business associate agreement, or other written agreement, with the CSP, the OCR will give great weight to this fact during its investigation.

Is a CSP ever considered to be a "conduit" (such as the postal service) and not a business associate that must comply with the HIPAA Rules?

A CSP is almost always considered a business associate when such CSP processes and/or stores ePHI for a covered entity. One exception to this rule is the limitation of transmission-only services of ePHI that do not include any form of storage of information other than on a temporary basis.[10] It is then that a CSP is considered a conduit rather than a business associate.

Is a CSP considered to be a business associate if it only receives and maintains information that has been de-identified (as per the HIPAA Privacy Rule)?

A CSP is not considered a business associate if the CSP only processes and/or stores information which has been de-identified pursuant to the requirements of the HIPAA Privacy Rule. Once PHI has been de-identified, such information is no longer considered to be protected information and the HIPAA Rules no longer restrict such use of information or the implementation of safeguards. OCR has issued guidance regarding the de-identification process.[11]

What if a covered entity (or its business associate) uses a cloud service provider to maintain electronic protected health information without first executing a business associate agreement with that CSP?

In the event a covered entity (or its business associate) utilizes a CSP for the processing and/or storing of ePHI prior to entering into a business associate agreement, such covered entity (or its business associate) is in direct violation of the HIPAA Rules.[12] Even where no business associate agreement exists between such covered entity and the CSP, a CSP that meets the definition of a business associate must adhere to the applicable HIPAA Rules.

There may be instances where a CSP is unaware that a covered entity (or its business associate) is utilizing its services for the purposes of creating, receiving, maintaining, or transmitting ePHI. If the CSP takes corrective action within thirty (30) days of receiving notification that its services are being used for these purposes, the HIPAA Rules provide for an affirmative defense.[13] However, the affirmative defense does not apply in cases where the CSP was not aware of the violation due to its own negligence.

Can a covered entity (or its business associate) use mobile devices to access electronic protected health information in the cloud under the HIPAA Rules?

Covered entities (and its business associates) may use mobile devices provided a HIPAA-compliant business associate agreement is in place between the all of the parties including the covered entity, the third-party service provider for the mobile device, and the CSP. HealthIT.gov has provided recommendations and tips regarding the use of mobile devices and securing ePHI.[14]

Is a CSP required to maintain electronic protected health information for a period of time following the completion of its services to a covered entity (or its business associate) under the HIPAA Rules?

The HIPAA Rules do not require a CSP to maintain ePHI for any time subsequent to the termination of its services with the covered entity (or its business associate). However, the HIPAA Privacy Rule states that a business associate agreement must stipulate that a business associate return or destroy all PHI upon the conclusion of the business associate agreement.[15] In some instances, when a CSP is unable to return or destroy the PHI, the business associate agreement shall include language to prevent any additional uses and/or disclosures when the return or destruction of PHI impractical.[16]

Under the HIPAA Rules, is a CSP who is a business associate required to provide documentation, or allow auditing, of its security practices by the covered entity (or its business associate)?

No. However, any covered entity (or its business associate) is required to acquire satisfactory assurances of a CSP's security practices and add such security provisions into its business associate agreement.[17] A CSP is accountable for any failure to safeguard the ePHI pursuant to the HIPAA Security Rule[18] and for unauthorized uses or disclosures.[19]

Is a CSP required to report a security incident if it involves a covered entity's (or its business associate's) electronic protected health information to the covered entity (or its business associate)?

In the event of a security incident (as defined by the attempt or successful unauthorized access, use, disclosure, modification, or destruction of ePHI),[20] a CSP is required, pursuant to HIPAA Security Rules,[21] to identify and respond to any and all security incidents and notify the covered entity. It is to be noted, however, that the description of details, frequency, and formatting of the incident reports should be outlined in the business associate agreement. If a security incident is deemed to be a breach, a CSP (or its business associate) is required under the HIPAA Breach Notification Rules to report such incident to the covered entity (or its business associate).[22] In addition, under the HIPAA Privacy Rule, a CSP, as a business associate, is also directly liable for the unauthorized access, use, disclosure, modification, or destruction of ePHI that has not been directly authorized in its business associate agreement with the covered entity.

In closing, the U.S. Department of Health & Human Services has established many processes, procedures, and protections in the utilization of CSPs. It is

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ultimately up to each covered entity, business associate, and CSP to understand, implement, and fulfill their obligations under the provisions of the HIPAA Rules. Should a breach occur, the OCR is authorized to issue fines for non-compliance which can rise to $1.5 million per each HIPAA violation. As technology changes around us, it is important to understand such changes in order to avoid these fines and fulfill the responsibilities under HIPAA.

Endnotes

1 Ms. Hunter practices in the areas of business law, employment law, taxation, trust and estates, and health care law focusing in the areas of compliance and audits pertaining to HIPAA. She is a graduate of the University of Florida, Levin College of Law with an LL.M. in Taxation (2002), and Stetson University College of Law with a Juris Doctorate (2001). She has been a member of the Florida Bar since 2003.

2 *See Guidance on HIPAA & Cloud Computing,* https://www.hhs.gov/hipaa/for-professionals/special-topics/cloud-computing/index.html.

3 *See* 45 C.F.R. § 160.103.

4 *Id.*

5 *See* https://www.hhs.gov/hipaa/for-professionals/covered-entities/sample-business-associate-agreement-provisions/index.html.

6 *See* 45 C.F.R. §164.308(a)(1)(ii)(A) and (B).

7 *See* http://nvlpubs.nist.gov/nistpubs/Legacy/SP/nistspecialpublication800-145.pdf.

8 78 Fed. Reg. 5,566, 5,572 (January 25, 2013).

9 A key used to encrypt and decrypt data, also called a cryptographic key, is "[a] parameter used in conjunction with a cryptographic algorithm that determines its operation in such a way that an entity with knowledge of the key can reproduce or reverse the operation, while an entity without knowledge of the key cannot." See NIST SP 800-47 Part 1 Revision 4, Recommendation for Key Management Part 1: General (January 2016). *Available at* http://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-57pt1r4.pdf.

10 *See* 78 Fed. Reg. 5,566, 5,572 (January 25, 2013). *See also,* https://www.hhs.gov/hipaa/for-professionals/faq/245/are-entities-business-associates/.

11 See https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/.

12 *See* 45 C.F.R. §§ 164.308(b)(1) and § 164.502(e).

13 *See* 45 C.F.R. § 160.410.

14 *See* https://www.healthit.gov/providers-professionals/how-can-you-protect-and-secure-health-information-when-using-mobile-device.

15 *See* 45 C.F.R. § 164.504(e)(2)(J).

16 67 Fed. Reg. 53181, 53254 (August 14, 2002).

17 http://www.hipaasurvivalguide.com/hitech-act-13401.php.

18 *See* http://www.hipaasurvivalguide.com/hitech-act-13401.php.

19 *See* 45 C.F.R. § 164.502(a)(3).

20 *See* 45 C.F.R. § 164.304.

21 *See* 45 C.F.R. § 164.308(a)(6)(ii) and 45 C.F.R. § 164.314(a)(2)(i)(C).

22 *See* 45 C.F.R. § 164.410 and OCR Breach Notification Rule (https://www.hhs.gov/hipaa/for-professionals/breach-notification/index.html).

Medical Marijuana Patient Consent

By Alan S. Gassman, JD, LLM and Seaver Brown JD, MBA[1]

Florida Statute § 499.0295 requires that a patient give written informed consent before being eligible to receive a doctor's recommendation to use medical marijuana. The requirements of the statute are further discussed below. Also provided below is a sample patient consent form.

By way of background, on November 8, 2016, Florida voters overwhelmingly approved the Florida Medical Marijuana Legalization Initiative, also known as Amendment 2, with nearly 71 percent in support of the Amendment. Amendment 2 will expand the use and availability of medical marijuana for those with specific debilitating diseases or medical conditions as determined by a licensed state physician.[2]

Nevertheless, the Florida Legislature and Department of Health have yet to provide any indication of when they will roll out the final rules and regulations for use of medical marijuana, leaving doctors, patients, and other caregivers without a solution to these chronic issues. The legislature must hash out the rules that will regulate if and when medical marijuana can be prescribed for those medical conditions set forth in Amendment 2, but before doing so should take a deep breath in order to decide exactly how they are going to accomplish this. Lawmakers are acutely aware that many issues will stem from these new rules.

On March 7, 2017, Representatives Jeff Brandes (Pinellas County), Darryl Ervin Rouson (Pinellas and Hillsborough Counties), and Greg Steube (Sarasota and Charlotte Counties) introduced Senate Bill No. 614, known as the Florida Medical Marijuana Act ("FMMA").[3] In a press release accompanying the Act, Senator Brandes stated that the FMMA would effectively repeal Florida's current medical marijuana laws and "replace them entirely with a broader set of regulations designed to encourage more participation from medical marijuana providers." Senator Brandes believes that Florida's current medical marijuana laws "promote a state-sanctioned cartel system that limits competition, inhibits access, and results in higher prices for patients. Florida should focus on what is best for patients."

Florida businesses and investors are abuzz over the opportunity to take part in a budding industry that would allow them to experience similar profitability as those do in states such as Colorado, Washington and California.

However, until the FMMA is enacted, doctors are still permitted to prescribe medical marijuana and low-THC products to patients suffering from diseases or medical conditions under the very restrictive Compassionate Medical Cannabis Act of 2014 (CMCA) and Right to Try Act of 2015 (RTTA).

There is obvious and well merited concern that medically prescribed marijuana will cause public harm when people under the influence drive, use it recreationally or inappropriately, or allow it to be used by children and young adults who may suffer from addiction, apathy, and other negative side effects. In addition, many members of the business and investment community would like to be in the business of growing, refining, and dispensing medical marijuana, which is sure to be a dynamic industry if the use of medical marijuana grows significantly, depending upon how strict the final rules and regulations will be.

The 2014 CMCA allows individuals suffering from cancer, chronic seizures, or severe muscles spasms to use low-THC, which contains less than 0.8 percent of tetrahydrocannabinol (the psychoactive compound found in marijuana). Allegedly, this provides all the medical benefits of medical marijuana without the euphoric feeling one obtains from ingesting normal marijuana plant leaves by smoking or eating, which contain an average of 20 percent THC.

The 2015 RTTA allows patients with a terminal illness[4] to use medical cannabis, which is derived from the whole plant and includes the psychoactive compound, THC. THC apparently induces an altered state of consciousness that allows many patients to escape the conscious feeling of pain, and apparently enhances the living experience in many ways for those who have used and encouraged it.

Physicians, advisors and patients should also be aware of the availability of Dronabinol (Marinol), which is a well-respected and under-used synthetic THC pharmaceutical product. The Mayo Clinic website states that "Dronabinol is used to prevent nausea and vomiting that may occur after treatment with cancer medicines. It is used only when other kinds of medicine for nausea and vomiting did not work. This medicine is also used to increase appetite in patients with acquired immunodeficiency syndrome (AIDS)."

The following "Informed Consent for Treatment With Medical Cannabis and/or low-THC Cannabis" is intended to be used by doctors and caregivers who will prescribe low-THC and medical marijuana to their patients under the CMCA or RTTA. It has not been approved by any malpractice insurance carrier, malpractice defense attorney, or health law firm.

Pursuant to Section 499.0295, Florida Statutes, a patient must give written informed consent before being eligible to receive a recommendation to use medical marijuana, which must include the following:

1. An explanation of the currently approved products and treatments for the patient's terminal condition.
2. An attestation that the patient concurs with his or her physician in believing that all currently approved products and treatments are unlikely to prolong the patient's life.
3. Identification of the specific investigational drug, biological product, or device that the patient is seeking to use.
4. A realistic description of the most likely

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outcomes of using the investigational drug, biological product, or device. The description shall include the possibility that new, unanticipated, different, or worse symptoms might result and death could be hastened by the proposed treatment. The description shall be based on the physician's knowledge of the proposed treatment for the patient's terminal condition.

5. A statement that the patient's health plan or third-party administrator and physician are not obligated to pay for care or treatment consequent to the use of the investigational drug, biological product, or device unless required to do so by law or contract.
6. A statement that the patient's eligibility for hospice care may be withdrawn if the patient begins treatment with the investigational drug, biological product, or device and that hospice care may be reinstated if the treatment ends and the patient meets hospice eligibility requirements.
7. A statement that the patient understands he or she is liable for all expenses consequent to the use of the investigational drug, biological product, or device and that liability extends to the patient's estate, unless a contract between the patient and the manufacturer of the investigational drug, biological product, or device states otherwise.

Please refer to the chart below for those conditions that will qualify for medical marijuana treatment under the present and proposed statutes:

Compassionate Medical Cannabis Act of 2014	Right to Try Act of 2015	Proposed Florida Medical Marijuana Act
Patient can use low-THC if suffering from: 1. Symptoms of cancer; 2. Chronic seizures; or 3. Severe and persistent muscles spasms.	Right to try medical marijuana if patient is suffering from a terminal illness, defined as: a. A progressive disease or medical or surgical condition; b. That causes significant functional impairment; c. That the treating physician does not believe to be reversible even with the administration of available treatment options approved by the FDA; and d. Without the use of life-sustaining procedures, will result in death within 1 year after diagnosis if the condition runs its normal course.	Full strength medical marijuana if suffering from specific debilitating diseases or including: 1. Cancer 2. Epilepsy 3. Glaucoma 4. HIV 5. AIDS 6. Post-traumatic stress disorder 7. Amyotrophic lateral sclerosis 8. Crohn's disease 9. Parkinson's disease 10. Multiple sclerosis, 11. Paraplegia, 12. Quadriplegia 13. A terminal condition; or 14. 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.

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SAMPLE CONSENT FORM

Informed Consent for Treatment With Medical Cannabis (marijuana) and/or low-THC Cannabis (marijuana)

Upon execution of this Informed Consent, I agree that I have been duly informed by my physician of the risks and effects associated with the therapeutic utilization of medicinal marijuana in the State of Florida. I have provided my physician with a detailed report of my medical history, such that they may be better suited to make this assessment of my medical condition and the recommendation that medicinal marijuana may be useful in relieving my symptoms. Further, I have not misrepresented my medical condition in order to obtain this recommendation and it is my intent to use marijuana only as need for the treatment of my medical condition, and not for recreational or non-medical purposes. I understand that it is my responsibility to be informed of, and adhere to all current and future state and federal laws regarding the possession, use, sale/purchase, and/or distribution of marijuana. I have been informed that the federal government has classified marijuana as a Schedule I controlled substance, which are defined, in part, as having: (1) a high potential for abuse; (2) no currently accepted medical use in treatment in the United States; and (3) a lack of accepted safety standards for use under medical supervision.

I have been informed of and understand the following: [**please initial each item**]

1a. (**FOR MEDICAL CANNABIS ONLY**) __ I understand that my terminal condition may currently be treated with FDA approved products and treatments.
As explained by my _____ and reiterated by the physician(s) at _____, my options include the following:
_____
_____
_____
_____

2a. (**FOR MEDICAL CANNABIS ONLY**) _____Upon meeting with my primary and/or specialty physician and discussing the various options available to me at this point in time, I concur with my physician's suggestion that all currently approved FDA products, treatments and medications are unlikely to prolong my estimated lifespan, and that the use of medical cannabis will provide me with a more natural and holistic approach to treating my symptoms than other currently available options.

1b. (**FOR LOW-THC CANNABIS ONLY**) _____ I understand that my seizures and/or spasms may currently be treated with medically acceptable alternatives.
As explained by my _____ and reiterated by the physician(s) at _____, my options include the following:
_____
_____
_____
_____

2b. (**FOR LOW-THC CANNABIS ONLY**) _____ Upon meeting with my primary and/or specialty physician and discussing the various options available to me at this point in time, I concur with my physician's suggestion that all currently approved FDA products, treatments, and medications are unlikely to improve symptoms of my physical condition producing seizures and/or spasms, and that the use of medical cannabis will provide me with a more natural and holistic approach to treating my symptoms than other currently available options.

3. _____ I understand that the specific investigational drug, biological product, or device I am seeking to use is cannabis, often referred to as marijuana. Currently, the Food and Drug Administration has not approved the "manufacture" of marijuana for medical use. Thus, any marijuana lawfully produced in a state will not be subject to the same sets of standards, quality control assurances, or other oversight mechanisms that conventionally accepted treatments and medications must adhere to. Until such time, each state will have a different set of standards in place to ensure some level of compliance with how marijuana is manufactured.

4. _____ Marijuana may contain unknown quantities of other active ingredients, impurities, or substances, in addition to THC, which is the primary psychoactive chemical component of marijuana. Further, due to the hybridization of different plant strains, genetic diversity between marijuana plants of the same species (i.e., indica vs. sativa) or variety can lead to significantly different effects on strength, effect, and duration of the psychoactive effects of marijuana. I accept these risks associated with consuming this product and hereby release (PHYSICIAN'S PRACTICE NAME) and its owners, shareholders, and employees from any liability due to the recommendation of and my use of this product.

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SAMPLE CONSENT FORM

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5. _____ I have been advised that marijuana is known to affect coordination, reaction times, motor skills, and cognition, i.e. the ability to think, judge and reason. While using marijuana, I will not drive, operate heavy machinery, or engage in any activities that require me to be alert and/or respond quickly. I understand that if I drive while under the influence of marijuana, I can be arrested for "driving under the influence."

6. _____ Potential side effects from the use of marijuana include, but are not limited to, the following: happiness, relaxation, euphoria, dizziness, shallow breathing, dilated pupils, anxiety, confusion, low blood pressure, loss of short term memory, difficulty completing complex tasks, decreased immune system, inability to concentrate, a distorted sense of time, impaired motor skills, slowed reaction times, paranoia, psychotic symptoms, general apathy, depression, restlessness, and/or increased appetite. There is the possibility that new, unanticipated, different, or worsened symptoms might result and death could be hastened by the proposed use of medical marijuana. Marijuana may also exacerbate schizophrenia in persons who were already predisposed to the disorder. Many medical authorities claim that use of cannabis, especially by persons younger than 25, can result in long-term problems with attention, memory, learning, a tendency to drug abuse, and schizophrenia. The physician(s) at (PHYSICIAN'S PRACTICE NAME) recommend cannabis use only for the relief of serious symptoms when all the above risks and sides effects are considered, and not for habitual use.

If filled in, the following describes further possible outcomes and side effects that might apply in my situation due to my current terminal condition:

_____

_____

_____

_____

7. _____ I understand that combining marijuana and alcohol is not recommended, and that additional side effects from using both may become present from such use. Cannabis should be treated as an open container of alcohol and should not be within reach in a vehicle.

8. _____ I agree to call (PHYSICIAN'S PRACTICE NAME) and my primary care doctor and any mental health counselor without delay, during normal business hours, if I experience any of the side effects listed above, and to immediately go to an emergency room if I have severe depression, psychotic symptoms, suicidal thoughts, or am experiencing severe crying spells. I will also contact an emergency room or dial 911 immediately if I experience respiratory problems, changes in my normal sleeping patterns, extreme fatigue, increased irritability, or begin to withdraw from my family and/or friends. If these symptoms occur outside the business hours of (PHYSICIAN'S PRACTICE NAME), I will call 911 or have myself transported to the nearest Emergency Room.

9. _____ Respiratory disease and/or cancer of the lung, mouth and tongue may develop from the vaporization or smoke inhalation of marijuana. Marijuana contains known carcinogens (cancer causing chemicals), and may contain harmful chemicals known as tars. If I begin to experience respiratory problems when using marijuana such as bronchitis, emphysema, and laryngitis, I will stop using it and report my symptoms to a physician.

10. _____ The use of marijuana to treat medical conditions has not been fully researched or approved by the FDA and Federal Government. As a result, the negative and positive effects associated with its use, drug interactions, and other medical risks cannot be accurately assessed. Before taking any current or future medications, or undergoing procedures for any medical condition, I understand that I will consult with my treating physician(s) before beginning or continuing to injest marijuana. Further, I understand that I should not discontinue any medication or treatment previously prescribed unless advised to do so by the treating physician(s).

11. _____ Individuals may develop a tolerance to, and/or habitual dependence on, marijuana. I understand that if I require increasingly higher doses to achieve the same benefit or if I think that I may be developing a dependency on marijuana, I should contact (PHYSICIAN'S PRACTICE NAME).

12._____ Signs of withdrawal can include the following: feelings of depression, sadness, irritability, insomnia, restlessness, agitation, loss of appetite, trouble concentrating, sleep disturbances, and unusual tiredness.

13. _____ Symptoms of marijuana overdose include, but are not limited to, nausea, vomiting, hacking cough, disturbances in heart rhythms, numbness in the hands, feet, arms or legs, anxiety attacks, and incapacitation. If I experience these symptoms, I agree to contact (PHYSICIAN'S PRACTICE NAME) immediately, call 911, or have myself transported to the nearest Emergency Room, whichever would provide the fastest treatment.

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SAMPLE CONSENT FORM

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14. _____ Unless required by federal or state law, or a valid contract entered into with my health plan provider, third-party administrator, or physician, I understand that I am responsible for all care and treatment costs that may result from my use of medical marijuana. **THIS DOCUMENT IS NOT AN EXAMPLE OF SUCH A CONTRACT. THERE IS NOTHING IN THIS DOCUMENT THAT OBLIGATES AN OWNER, SHAREHOLDER, OR EMPLOYEE OF (PHYSICIAN'S PRACTICE NAME) TO ASSIST WITH OR COVER ANY COSTS ASSOCIATED WITH MY USE OF FULL MEDICAL OR LOW-THC CANNABIS.**

15. _____ I also understand that I alone am liable for all expenses consequent to the use of marijuana, and that liability extends to my estate, unless an agreement between myself and the manufacturer of the medical marijuana or device states otherwise.

16. _____ If the physician(s) or any of the staff of (PHYSICIAN'S PRACTICE NAME) subsequently learns that the information I have furnished is false or misleading, the recommendation for marijuana may no longer be valid. I agree to promptly meet with the physician(s) or any of the staff of (PHYSICIAN'S PRACTICE NAME) and/or provide additional information in the event of any inaccuracies or misstatements in the information I have provided. **I UNDERSTAND THAT I WILL INCUR THE ADDITIONAL COSTS ASSOCIATED WITH THIS ADDITIONAL VISIT, EVEN IF IT IS NOT AT A REGULARLY SCHEDULED INTERVAL.**

17. _____ I have had the opportunity to discuss these matters with the physician and to ask questions regarding anything I may not understand or that I believe needed to be clarified. I acknowledge that the physician(s) at (PHYSICIAN'S PRACTICE NAME) has/have informed me of the nature of a recommended treatment, including but not limited to, any recommendation regarding medical marijuana. I have been informed of the risks, complications, and expected benefits of any recommended treatment, including its likelihood of success and failure. I acknowledge that the physician(s) at (PHYSICIAN'S PRACTICE NAME) has/have informed me of any alternatives to the recommended treatment, including the alternative of no treatment, and the risks and benefits thereof.

18. _____ I understand the following are not permitted: The possession, use, or administration of cannabis by smoking; the transfer of cannabis to a person other than the qualified patient for whom it was ordered; the use of cannabis on any form of public transportation, in any public place, in a qualified patient's place of employment (if restricted by his or her employer), in a state correctional institution, on the grounds of a preschool, primary school, or any school bus or vehicle.

19. _____ I understand that I cannot receive more than a 45-day supply of medical marijuana. I agree to see the physician(s) or other authorized provider at (PHYSICIAN'S PRACTICE NAME) on a monthly basis. The 45-day allowance is to be viewed as an occasional grace period that may be used in the event of travel or other uncommon need. The expectation is that I will be seen monthly at (PHYSICIAN'S PRACTICE NAME).

20. _____ I understand that my information will be entered into and updated periodically within the Compassionate Use Registry, a database within the Florida Department of Health. My marijuana recommendation will be entered electronically into the system. Any licensed dispensary will be able to access my information and then fulfill the order that is entered by the physician(s) or other authorized provider at (PHYSICIAN'S PRACTICE NAME). I am responsible for obtaining and properly using the therapy.

21. _____ If I provide any dishonest or untruthful information, I will be discharged as a patient by (PHYSICIAN'S PRACTICE NAME).

22. _____ I may be asked to provide a urine drug sample on my first and/or subsequent evaluation(s) for medical cannabis. If the in-office analysis shows a positive result for illegal substances, the physician may elect to defer placing an order for medical cannabis on that visit. Depending on the confirmation result, it is possible that I may no longer obtain medical cannabis from (PHYSICIAN'S PRACTICE NAME). I further understand that medical marijuana may not be indicated for my medical condition. The physician(s) at (PHYSICIAN'S PRACTICE NAME) will only order medical cannabis if it is an indicated therapy. Therefore, I understand that my payment is for the physician evaluation and NOT in exchange for medical cannabis (marijuana). Thus, I agree that a refund for services rendered will not be provided if, for any reason, the physicians(s) elect not to recommend medical cannabis.

23. _____ I understand that physicians who recommend medical marijuana must submit the details of that recommendation to the UF College of Pharmacy. I accept the following statement: University of Florida has no role in treatment of any patient or determination for efficacy or safety of medical marijuana being prescribed by any physician. The UF College of Pharmacy is merely receiving data (including physicians' treatment plans for patients) for any potential future research on medical marijuana efficacy and safety generally (not for individual patients), if dedicated funds were to be provided by the state for this purpose in the future. Each patient's consent to treatment with marijuana prescribed by a physician, including the statutorily required submission by the physician of treatment plans to the College, includes the patient's acknowledgment of and consent to the absence of any treatment or safety related role of the University of Florida.

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SAMPLE CONSENT FORM

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24. _____ I understand that my eligibility for hospice care may be withdrawn if I begin treatment with medical marijuana, however hospice care may be reinstated if I end the treatment with marijuana and continue to meet all hospice care eligibility requirements.

Upon signing below, I agree that I have been advised by my physician and fully infoRmed of all other approved products or treatments available for my condition. I further agree that my physician has discussed the relative risks and side effects associated with the use of medical cannabis, and the potential harm it could have on my overall health. Finally, due to my physician's recommendation or ordering of low-THC or medical cannabis, I agree that I have disclosed to my physician all other products, treatments, and/or medications I am currently prescribed or otherwise taking to treat my condition, as they may also have an adverse effect on my health.

Patient Name (printed): _____

Patient Signature: _____ Date: _____

Endnotes

1 **Alan S. Gassman, J.D., LL.M.** is a board certified estate planning and trust lawyer who practices in Clearwater, Florida. He is the lead author of several books, including *Gassman & Markham on Florida and Federal Asset Protection Law, Creditor Protection* for *Florida Physicians,* and *A Practical Guide to Kickback and Self-Referral Laws for Florida Physicians* (with Lester Perling). He has served as the co-chair of both The Florida Bar Wealth Protection Conference and The Florida Bar Representing the Physician Conference each year for more than fifteen years.

Seaver Brown, J.D., MBA is an attorney with a law degree from Florida Coastal School of Law and a Masters in Business Administration from Jacksonville University. He also attended the University of South Carolina where he graduated with a degree in Business Administration and a concentration in Finance. He was admitted to the Florida Bar in 2015 and is presently engaged in professional writing, research, and mathematical modeling and spreadsheet design for Gassman, Crotty & Denicolo, P.A.

2 These diseases include: cancer, epilepsy, glaucoma, HIV, AIDS, post-traumatic stress disorder, amyotrophic lateral sclerosis, Crohn's disease, Parkinson's disease, multiple sclerosis, paraplegia, quadriplegia, a terminal condition, 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.

3 These representatives appear to be influential this arena. Bill available at https://www.flsenate.gov/Session/Bill/2017/0614 (this is one of several bills pertaining to medical marijuana that the Florida Legislature is considering during the current legislative session).

4 Defined as, "a progressive disease or medical or surgical condition that cause significant functional impairment, is not considered by a treating physician to be reversible even with the administration of available treatment options currently approved by the FDA, and, without the administration of life-sustaining procedures, will result in death within 1 year after diagnosis if the condition runs its normal course." Fla. Stat. § 499.0295.

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cooperation credit or consideration in negotiation a corporate entity will be required, not just to disclose information about individuals it already possessed, but also to seek out and learn facts of interest to the government about individuals involved in alleged wrongdoing. The government will also consider how quickly the entity cooperated, the diligence and completeness, and more. For healthcare providers, particularly partnerships, this means FCA accusations alone, including those brought by *qui tam* relators, can initiate the partner versus partner "race to the courthouse" previously seen in organized crime investigations, where individuals who fear criminal prosecution try to be the first to cooperate with the government, hoping to exchange their testimony for leniency.

The Memo announced a change in focus, even in response to *qui tam* claims naming only an entity as a defendant–"[b]oth criminal and civil attorneys should focus on individual wrongdoing from the very beginning of any investigation of corporate misconduct."[7]

The Yates Memo called for closer cooperation and communication between the government's civil attorneys and criminal prosecutors.

Settlements of corporate cases should not provide protection for any individuals and should include a clear plan to bring actions against individuals within applicable statutes of limitations. For small- and medium-sized healthcare providers, including partnerships, this means that even the most draconian settlement made to avoid the risks of FCA litigation offers no relief from the exact same allegations for the individual members of the company.

Finally, the Yates Memo directed the government to bring actions against any defendant, regardless of the entity or individual's ability to pay a significant judgment, in order to punish bad actors and serve as a warning for others.

In 2016, the provider community began to see the results of the Caldwell announcement and the Yates memo.

In September 2016, North American Health Care, Inc. (NAHC), settled allegations of billing for medically unnecessary rehabilitation therapy services for $28.5 million. But, the settlements did not stop with NAHC. Its chairman of the board agreed to pay $1 million and one of its senior vice presidents agreed to pay $500,000 as part of the deal. The government's own press release clearly stated that these settlements were not based upon any finding of wrongdoing:

> The claims resolved by the settlements are allegations only and there has been no determination of liability.[8]

The other big individual liability settlement came a year after Tuomey Healthcare's $72.4 million corporate FCA resolution. Tuomey's former CEO settled with the government for $1 million, with a waiver by him of any claim against Tuomey for his loss. While the government prevailed in its trial against Tuomey Healthcare, it never won a verdict against the CEO. Again the government's press release made clear that the settlement was not founded upon any finding of actual wrongdoing:

> The claims resolved by the settlement with Cox are allegations only, and there has been no determination of his individual liability.[9]

But the government's targeting of individuals was not saved for its blockbuster settelments against large defendants, smaller providers felt the newly implemented policies as well. In smaller cases, the government brought claims and forced settlements against individuals. In Jacksonville, Florida, the U.S. Attorney announced a settlement against owners of a compound pharmacy, QMedRx, even before there was any finding of liability against the pharmacy.[10] Similarly, a Nashville pharmacy, Nashville Pharmacy Services, LLC, and its majority owner settled a whistleblower case alleging improper waiver of co-pays.

Moving forward, the government's focus on individuals rather than just entities will become the rule rather than the exception. This will include criminal investigations by the FBI as well as HHS. It will also mean that individuals will be forced to settle fraud lawsuits in order to avoid the enormous risk of FCA litigation, even without a showing of actual misconduct.

Increased Penalties

The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 took effect in November, 2015. The new law required that the Program Fraud Civil Remedies Act and the False Claims Act (FCA) penalties be adjusted for inflation and then that the penalties be adjusted for inflation each following year.

In 1996, under the Debt Collection Improvement Act of 1996, the minimum and maximum penalties under the FCA were increased to $5,500 and $11,000, respectively. Practitioners expected the correction to run from that date, leading to an increase of approximately 140% with a maximum penalty of about $15,000. Instead, the government disregarded that correction because it was subject to the 10% cap set forth in the 1996 Act. The government went all the way back to 1986, leading to a massive 216% penalty increase.

All new *qui tam* actions will include penalties from $10,781-$21,563, more than double the penalties faced during the past ten years.[11] The FCA's treble damages penalty was not changed as part of this adjustment.

To government contractors, including Medicare and Medicaid providers, this is a foreboding change. The FCA was always onerous, to the point that some defendants invoked the Constitution's Eighth Amendment prohibition against excessive fines, though no case ever turned upon that issue. This massive increase may well put that defense back in play, particularly for claims that are microscopic in comparison to the penalties (e.g., a $5.00 laboratory service leading to a $21,563 penalty). While penalties are often not included as part of negotiated settlements, they are mandated for any case decided by a court. It is this threat that often makes settlement discussions feel like coercion or extortion to contractors.

These changes affect penalties assessed after August 1, 2016 for violations that occur after November 2, 2015.[12] This includes any retained overpayment unreturned after more than 60 days under the Final Rule.

False Certification and Materiality

Most False Claims Act cases are easy to understand. They involve claims that are factually false (e.g. a bill for an office visit or an operation that did not actually occur). Claims for services that are not medically necessary and criminal violations such as payments of kickbacks in exchange for Medicare referrals, also fall under this category.

But another category of FCA violations is less obvious. After the 1986 amendments to the FCA, the government and whistleblowers started filing FCA cases based upon a theory of *false certification*. False certification cases allege that a claim is legally false, not factually false. A claim is legally false if it violates an

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underlying legal requirement, such as the a statute or regulation. False certification claims take one of two forms: express false certifications or implied false certifications. Express false certification has been accepted as a theory of FCA liability for decades.

Implied False Certification Claims

A more controversial extension of false certification is the theory of *implied false certification*. Under this theory, a claim submitted to the government impliedly certifies compliance with all applicable statutes and regulations. Historically, courts approached the theory with more hesitation because there was no knowingly false certification or claim to connect the FCA allegations to. The skepticism created fissures, dividing the federal appellate courts into three camps, those that rejected the theory, those that accepted it where the statute or regulation at issue was explicitly identified as an express condition of payment,[13] and one, the First Circuit, that adopted it without express limitation.

The Supreme Court resolves the conflict, and creates a new rule.

In June 2016, the Supreme Court of the United States remedied the circuit split and issued the most anticipated FCA opinions in years: *Universal Health Services, Inc. v. United States ex rel. Escobar.*[14]

The FCA case was based upon the theory that counseling at *Universal Health Services* was provided by practitioners who were not properly licensed according to state regulations. However, the counseling was actually provided, and the licensing regulations did not specifically condition payment upon compliance. This is an implied certification theory as the submitted claims were not false but the submission of the claims impliedly certified compliance with other statutes and regulations.

The defendant argued that the implied certification theory could not apply unless the statute or regulation violated explicitly stated reimbursement was conditioned upon such compliance.

The government, on the other hand, argued that implied certification was sufficient to make the falsity material. Additionally, the government argued, any claim submitted in violation of a statute or regulation that was an express condition of payment, no matter how trivial, would be a *per se* violation of the FCA.

The Court rejected both arguments, ruling that implied false certification was a valid basis for pursuing FCA cases but only if the falsity was material to government payments.

Returning to the statute, the Court cautioned that the FCA imposes liability only for false statements which can only be proved under a theory of implied false certification if:

1. The claim asserts specific representations about the goods or services provided; and
2. The defendant "fail[s] to disclose noncompliance" with a material legal requirement "makes those representations misleading half-truths."

The Court then addressed whether only those requirements identified by regulation or statute as conditions of payment (rather than conditions of participation) are sufficient under the theory.The Court first rejected the argument that an implied certification case requires an explicit condition of payment. Rather, the violation must be found material under a fact-based analysis. For example, if a provider knows or should know that the government would not reimburse a claim if it knew of the violation it is material– regardless whether a statute, regulation, or contract explicitly identifies it as a condition of payment. Similarly, if a provider knows that the government historically refused to pay similar claims due to such violations, submission of such claims could create FCA liability.

The Court then rejected the government's argument that all explicitly identified conditions of payment are material under the FCA. The Court ruled that only the government's actual payment decision is relevant to determining materiality–not an arbitrary categorization. For example, if the government routinely pays claims submitted in violation of a regulatory requirement identified as a condition of payment, such a violation is immaterial to the payment decision and therefore could give rise to an FCA claim.

The Court's rejection of both parties' arguments clearly staked out the rule moving forward: knowledge and materiality remain the touchstone of an FCA action, not an arbitrary classification of a specific requirement.

On first blush, *Universal Health Services* appeared to be a tremendous victory for the government and for whistleblowers. Regulations of every type, not just those explicitly tied to payment of claims, could support an FCA lawsuit. The Court's materiality test seemed more difficult to resolve early in a case via motions to dismiss or for summary judgment. That, in turn, could mean more settlements, as providers could hardly risk a verdict against them with the newly increased FCA penalties.

Whether or not the landscape has dramatically shifted against defendants remains unknown but subsequent 2016 FCA rulings highlighted that *Universal Health Services* is at best a double-edged sword for the government and whistleblowers.

The Supreme Court's ruling on materiality rebutted any attempts to whittle away at the requirement's high-burden: "[t]he materiality standard is demanding [and] looks to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.[15] Moreover, such a misrepresentation is only material "if it would likely induce a reasonable person to manifest his assent."[16] Though the Supreme Court opened the door to implied certification claims, it reinforced the demanding materiality standard.

The government is pushing back against the Supreme Court's materiality test.

This reinforced application of materiality quickly drew legal attacks. In an *amicus* brief submitted in a case before the Eleventh Circuit[17] the government argued that the term "material" is already defined under the FCA as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property"[18] and this definition remained unchanged by *Universal Health Services*:

> Although the Court in *Universal Health Services* described the materiality requirement as "demanding," and clarified that a violation is not material because the government has the legal right to refuse payment because of that violation, no matter how insubstantial, nothing in *Universal Health Services* actually imposed a heightened test beyond the "natural tendency" test codified in the False Claims Act, entrenched in the common law, and applied in numerous courts of appeals.[19]

The government argued that the natural tendency test required a "holistic" approach to materiality; a focus on the "tendency or capacity of the undisclosed violation to affect the government decision

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maker."[20] The government's goal was to remove any post-*Universal Health Services* "requirement that [a] misrepresentation be likely to affect the ultimate decision itself."[21] Indeed, it went so far as to argue that the Supreme Court's fact-based analysis was neither exhaustive nor individually dispositive because materiality rests on whether a violation has a natural tendency to influence the decision to pay a claim. Under this approach, any determination on materiality will "likely . . . be a determination for a jury" rather than a legal determination for a court.[22]

The government's position is directly contrary to the Supreme Court's ruling. If it were adopted, implied certification cases based upon a holistic approach could never be resolved at the summary judgment stage. This, in turn, would lead to many more coerced settlements from healthcare providers who cannot risk the massive FCA penalties in front of a jury, but who, under the *Universal Health Services* standard of materiality, could prevail prior to trial.

Conclusion

The year 2016 was significant in the evolution of the FCA. The massive and unexpected increase in penalties will certainly lead to higher recoveries for the government. However, it will also lead to settlements coerced out of innocent providers who cannot face the risk of an FCA trial. The application of the recent DOJ policies as laid out by Ms. Caldwell and Ms. Yates will pit providers against providers, partners against partners, as they seek credit for cooperation and the best available deal with the government. Perhaps most interesting of all, the Supreme Court's decision in *Universal Health Services* will be picked apart, interpreted, and applied for years to come, as the courts figure out how far implied false certification can be stretched and how the materiality test is to be applied under different legal and factual scenarios.

Endnotes

1 This article is an excerpt from the upcoming book, *Healthcare and the False Claims Act, 2016*, from Healthlaw Publishing LLC. A free copy can be ordered at http://healthlawpublishing.com/2017/02/10/healthcare-and-the-false-claims-act-2016/.

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3 Remarks by Assistant Attorney General for the Criminal Division Leslie R. Caldwell at the Taxpayers Against Fraud Education Fund Conference, JUSTICE NEWS (September 17, 2014), https://www.justice.gov/opa/speech/remarks-assistant-attorney-general-criminal-division-leslie-r-caldwell-taxpayers-against.

4 *Id.*

5 Yates, Sally, *Individual Accountability for Corporate Wrongdoing*, USDOJ (September 9, 2015) https://www.justice.gov/dag/file/769036/download.

6 *Id.* at 2.

7 *Id.* at 4.

8 *North American Health Care Inc. to Pay $28.5 Million to Settle Claims for Medically Unnecssary Rehabilitation Therapy Services*, USDOJ (September 19, 2016) https://www.justice.gov/opa/pr/north-american-health-care-inc-pay-285-million-settle-claims-medically-unnecessary.

9 *Former Chief Executive of South Carolina Hospital Pays $1 Million and Agrees to Exclusion to Settle Claims Related to Illegal Payments to Referring Physicians*, USDOJ (September 7, 2016) https://www.justice.gov/opa/pr/former-chief-executive-south-carolina-hospital-pays-1-million-and-agrees-exclusion-settle.

10 *United States Settles False Claims Act Allegations Against Compound Pharmacy Owners For $7.75 Million 2016*, USDOJ (September 14, 2016) https://www.justice.gov/usao-mdfl/pr/united-states-settles-false-claims-act-allegations-against-compound-pharmacy-owners-775.

11 The maximum Civil Monetary Penalty was increased to $10,781.

12 The DOJ stated that penalties associated with violations that occurred prior to November 2, 2015, the date the Bipartisan Budget Act went into effect, will still be subject to the old penalties.

13 The Eleventh Circuit fell under this second category.

14 136 S. Ct. 1989 (2016).

15 *Universal Health Services*, 136 S. Ct. at 2003.

16 *Id.*

17 Brief for the United States as Amicus Curiae, *United States ex rel. Marsteller v. Tilton, et al.*, Case No. 16-11997 (11th Cir., Aug. 25, 2016).

18 31 U.S.C. § 3729(b)(4) (2016).

19 *Id.* at 17.

20 *Id.* at 16.

21 *Id.* at 10.

22 *Id.* at 20.

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