THE FLORIDA BAR
Health Law Section Newsletter
THE RESOURCE FOR FLORIDA HEALTH LAW
The Florida Bar Health Law Section
Vol. XVII, No. 10 www.flabarhls.org Fall 2016

INSIDE:

Understanding *Escobar*: A Demanding Materiality Standard for the Implied False Certification Theory

By Jennifer D. Brechbill, Stephanie L. Carman, Natalie T. Sinicrope & Samantha G. Spiro[1]

On June 16, 2016, the Supreme Court issued its opinion in *Universal Health Services, Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016). The case involved a young patient's treatment at a mental health clinic from unlicensed or unsupervised providers. The case presents both tragic circumstances and far-reaching legal significance. In an opinion delivered by Justice Clarence Thomas, the Court clarified the controversial implied false certification theory and its application to the False Claims Act ("FCA").

What is the Implied False Certification Theory?

According to the implied false certification theory, when a defendant submits a claim to the government, it impliedly certifies compliance with all payment conditions. If that claim fails to disclose the defendant's violation of a "material statutory, regulatory, or contractual requirement," the defendant has made a misrepresentation that renders the claim "false or fraudulent" under the FCA.[2]

Prior to *Escobar*, circuit courts were divided on whether the implied false certification theory could be a basis for FCA liability. Some held that FCA liability could be premised on the implied false certification but limited its scope.[3] Others either rejected the theory completely, holding that only an express falsehood can render a claim false[4], or refused to address the issue.[5]

Courts were also divided on whether FCA liability may *only* attach when the purported violation was of a requirement that was expressly identified by the government as a condition of payment. Some jurisdictions, such as the District of Columbia and Fourth Circuits, like the First Circuit, rejected that standard for liability.[6] Conversely, the Second Circuit has held that FCA liability attaches only when defendants fail to disclose violations of express conditions of payment.[7]

Escobar addressed these circuit splits in a unanimous opinion.

Oral Argument

It is perhaps surprising that the Court issued a unanimous opinion in light of the April 19, 2016 oral argument, which showed some disagreement on the Court. At the extremes, Chief Justice John Roberts appeared sympathetic to the defense, while Justice Sonia Sotomayor was decidedly not. Yet, all of the justices seemed to focus on the issue of "materiality." They seemed to agree that limiting FCA liability to falsity appearing on the face of a claim would be too restrictive. As Justice Elena Kagan explained, "I'm not into every jot and tittle. I'm into material portions of the contract. That – you know, that the guns shoot, that the boots can be worn, that the food can be eaten -- . . . and a doctor's care is a doctor's care."[8]

The Court Held That In Certain Circumstances, Implied False Certification Can Be a Basis for Liability

The Court held that the implied false certification theory can be a basis for FCA liability, at least where two conditions are satisfied: (1) the claim does not merely request payment, but also makes specific representations about the

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CMS Issues 2016 Update: What Health Care Providers Need to Know Regarding Medical Marijuana in Florida[1]

By: Erin Smith Aebel, Board Certified Health Lawyer, Rachel B. Goodman and Jessica S. West[2]

Medical Marijuana in Florida

Florida has enacted laws permitting Florida licensed physicians to order medical marijuana, in the limited forms of low-THC cannabis and medical cannabis (hereinafter collectively referred to as "medical marijuana"),[3] for their patients in compliance with state laws and regulations.[4] In November, Florida residents will vote on a revised proposed amendment to the Florida Constitution, called Amendment 2, potentially expanding the law regarding medical marijuana in the state. As patient demand for medical marijuana for various physical conditions increases, it is important for health care providers and their counsel to understand the current requirements for ordering and treating qualified patients with low-THC cannabis and medical cannabis. The purpose of this article is to provide an update on the current status of the medical marijuana laws in Florida and clarify what is required of Florida licensed physicians interested in treating qualified patients in compliance therewith. It is necessary to keep in mind that while distinguished technically from the "ordering" of medical marijuana under Florida law, the "prescribing" of medical marijuana remains illegal under federal law.

March 2016 Changes to Florida's Medical Marijuana Laws

Florida law regarding low-THC cannabis dates back only to June of 2014, when Governor Rick Scott signed Senate Bill 1030 into law, thereby enacting The Compassionate Medical Cannabis Act of 2014.[5] At that time, the act established a system to grow, cultivate, distribute, and prescribe certain low-THC strains of medical marijuana (referred to herein, including any amendments thereto, as the "Cannabis Act").[6] As originally enacted, the statute only decriminalized the use of low-THC cannabis, exclusively in the form of oil or vapor, and specifically excluded administration of the low-THC cannabis by smoking.[7]

The following year, in May of 2015, Governor Rick Scott signed into law Florida's Right to Try Act, allowing eligible, terminally ill patients to access investigational drugs, biologic products or devices that have successfully completed phase 1 of a clinical trial but have yet to receive approval for general use by the Food and Drug Administration (referred to herein, including any amendments thereto, as the "RTTA").[8] At the time the RTTA was enacted, like the Cannabis Act, it did not apply to medical cannabis.

Prior to recent amendments, Florida law only permitted licensed physicians to order *low-THC cannabis*[9] for qualified patients. In March of 2016, Governor Rick Scott signed into law House Bill 307 and House Bill 1313 ("HB307/HB1313") making, for the first time, *medical cannabis*[10] available to terminally ill patients under certain conditions, and thereby also expanding the types of medical marijuana that can be grown and sold in Florida. The amendments also set forth additional regulatory standards about safety and security, labeling, physician ordering qualification criteria, use of independent treating laboratories, and Florida Department of Health ("FDOH") oversight, among other changes, to the preexisting law.

With the enactment of HB307/HB1313, in addition to low-THC cannabis, medical cannabis can be ordered by authorized Florida physicians under the Cannabis Act for individuals who meet the definition of an "eligible patient" under the RTTA. The term "eligible patient" is defined "as a person who (1) has a terminal condition that is attested to by the patient's physician and confirmed by a second independent evaluation by a board-certified physician in an appropriate specialty for that condition; (2) has considered all other treatment options for the terminal condition currently approved by the United States Food and Drug Administration; (3) has given written informed consent for the use of an investigational drug, biological product, or device; and (4) has documentation from his or her treating physician that the patient meets the requirements of this paragraph."[11] The RTTA then defines "terminal condition" to mean

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Notes from the Chair

The Fall meeting of the Executive Council for the Health Law Section took Place on September 15 at the Rosen Centre in Orlando. After dispensing with administrative details and hearing the various committee reports the Board discussed future plans for the Section, as well as current issues of interest to our members.

One area of particular interest was the conversation around The Florida Bar President William Schifino's recent communications regarding the Constitution Revision Commission ("CRC") of 2017. Under an existing provision of Florida's Constitution, the CRC is a 37 member panel created every 20 years to consider revisions to the state's constitutional charter. The 37 members are appointed by the Governor, the Senate President, the House Speaker, and the Chief Justice of the Florida Supreme Court. The Attorney General of the State also sits as member on the Panel. Appointments will be finalized in February of 2017.

Of particular note is that Florida Chief Justice Jorge Labarga will make three appointments to the CRC. These appointments will likely be critical to discussions regarding term limits (for judges), funding (for public defenders) and the future role of The Florida Bar in our state. Individuals interested in being considered for membership on the CRC may submit a resume to http://www.floridasupremecourt.org/pub_info/crc.shtml.

A second area of interest that was discussed dealt with the recent (February 2016) release of findings by the Bar's Young Lawyers Division ("YLD") from its Survey on Women in the Legal Profession. In compiling the survey responses from female members of the YLD, over 43% of the respondents reported experiencing one or more instances of gender bias over the course of their careers. This high percentage was of particular concern to President Schifino who outlined his intent to convene a taskforce charged with exploring the issue further, and to release a follow up survey on gender bias to all Bar members. It is his hope to increase the dialogue on this issue, and find a workable solution to the problem.

The Health Law Section is fully committed to working on these and other matters of interest to our membership. We would welcome your input and participation. As always, the meetings of the Health Law Executive Council are open to both current and future members of the Health Law section. The next meeting of the Health Law Executive Council is scheduled for February 2, 2017 in Orlando at the Rosen Center Hotel. I hope that you will join us.

Steven Grigas

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"a progressive disease or medical or surgical condition that causes significant functional impairment, is not considered by a treatment physician to be reversible even with the administration of available treatment options currently approved by the United States Food and Drug Administration, and, without the administration of life-sustaining procedures, will result in death within 1 year after diagnosis if the condition runs its normal course."[12] Even as amended, the Cannabis Act and the RTTA prohibit administration of low-THC cannabis or medical cannabis by smoking.

The Cannabis Act and the RTTA set forth particular requirements that a physician in Florida must satisfiy before he or she can order low-THC cannabis or medical cannabis for a qualified patient. Notably, physicians licensed under chapters 458 and 459, Florida Statutes, are required to take an 8-hour course and subsequent exam offered by the Florida Medical Association or the Florida Osteopathic Medical Association before ordering low-THC cannabis or medical cannabis for qualified patients.[13] These courses are currently offered by the Florida Medical and Osteopathic Associations and have been completed by 127 physicians as of September 17, 2016.[14] Failure to follow the guidelines established in the Cannabis Act is a first-degree misdemeanor, punishable by imprisonment for up to one year or $1,000.00 in fines.[15]

Requirements for Authorized Ordering

Under the Cannabis Act, a qualified physician is authorized to (1) order low-THC cannabis to (a) treat a qualified patient suffering from cancer or a physical medical condition that chronically produces symptoms of seizures or severe or persistent muscle spasms; or (b) to alleviate symptoms of such disease, disorder, or condition, if no other satisfactory alternative treatment options exist for the qualified patient; (2) order medical cannabis to treat an eligible patient as defined in the RTTA; or (3) order a cannabis delivery device[16] for the medical use of low-THC cannabis or medical cannabis, but only if the physician:

Holds an active, unrestricted Florida license as a physician under chapter 458 or an osteopathic physician under chapter 459 and meet the above described education requirements;

Has treated the patient for at least 3 months immediately preceding the patient's registration in the compassionate use registry;

Has determined that the risks of treating the patient with low-THC cannabis or medical cannabis are reasonable in light of the potential benefit to the patient. For patients younger than 18 years of age, has obtained concurrence of this determination from a second physician, and such determination is documented in the patient's medical record;

Registers as the orderer of low-THC cannabis or medical cannabis for the named patient on the compassionate use registry maintained by the FDOH and updates the registry to reflect the contents of the order, including the amount of low-THC cannabis or medical cannabis that will provide the patient with not more than a 45-day supply and a cannabis delivery device needed by the patient for the medical use of low-THC cannabis or medical cannabis.[17] The physician must also update the registry within 7 days after any change is made to the original order to reflect the change. The physician must deactivate the registration of the patient and the patient's legal representative when

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treatment is discontinued;

Maintains a patient 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 or medical cannabis;

For low-THC cannabis, submits the patient treatment plan quarterly to the University of Florida College of Pharmacy for research on the safety and efficacy of low-THC cannabis and medical cannabis to patients;

For low-THC cannabis, obtains the voluntary written informed consent of the patient or the patient's legal representative to treatment with low-THC cannabis 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;

For medical cannabis, obtains written informed consent as defined in and required under the RTTA, if the physician is ordering medical cannabis for an eligible patient pursuant to the RTTA; and

Is not a medical director employed by a dispensing organization.

The Office of Compassionate Use and the Compassionate Use Registry

Pursuant to the Cannabis Act, the FDOH was required to and did establish the Office of Compassionate Use ("OCU").[18] The FDOH was also required to create a "compassionate use registry" where ordering physicians are to register qualified patients. Notwithstanding a number of legal challenges, the FDOH and the OCU engaged in the task of rulemaking, with their efforts ultimately culminating in final rules, which became effective on June 17, 2015. [19]

On November 23, 2015, the FDOH approved five dispensing organizations that met the requirements of Florida Statutes, Section 381.986, and Chapter 64-4, of the Florida Administrative Code. In addition to the changes described above, HB307/HB1313 also allows for three additional dispensing organizations to qualify for approval once 250,000 patients register with the compassionate use registry. As of September 17, 2016, there are six approved dispensing organizations. Currently, two of those dispensing organizations, Trulieve in Gadsden County, and Surterra Therapeutics in Hillsborough County, are open for business and have commenced sale and delivery of low-THC cannabis products to registered patients across the state. At this time, medical cannabis is only available through Trulieve, though Surterra expects to begin providing medical cannabis to registered patients later this year.

Amendment 2

In November of 2014, shortly after the Cannabis Act was originally signed into law, Florida voters had the opportunity to vote on a proposed amendment to create a new section 29 to article X of the Florida Constitution, commonly referred to as "Amendment 2." The amendment, which would have expanded the type of medical marijuana available to Floridians, as well as the class of qualified patients, was ultimately defeated. Despite obtaining more than fifty-seven percent of votes in favor of the amendment, the votes fell just shy of the necessary 60 percent required to pass a constitutional amendment in Florida.

Notwithstanding, Florida voters will have another chance to vote on a proposed amendment to create a new section 29 to article X of the Florida Constitution regarding medical marijuana in November 2016. Also referred to as "Amendment 2," the updated proposed amendment similarly strives to broaden the circumstances under which medical marijuana could be ordered for a patient.[20] In contrast to the current laws, Amendment 2 does not specifically prohibit administration of medical marijuana by smoking. However the new proposed amendment is narrower than its 2014 predecessor in that it more narrowly defines a "debilitating medical condition" and requires parental consent for underage patients.

Medical Marijuana Remains Illegal Under Federal Law

Physicians should be aware, and their attorneys should point out,[21] that despite state law decriminalizing certain types and uses of medical marijuana in the state of Florida, marijuana remains illegal in the United States, even for medical use. Thus, under federal law, a physician cannot lawfully prescribe marijuana to a patient.[22] Notably, on August 11, 2016, the U.S. Department of Health and Human Services and the Drug Enforcement Administration denied two petitions seeking to reschedule marijuana under the Controlled Substances Act.[23] Simultaneously, however, the DEA took action to allow for additional medical marijuana research studies by increasing the number of authorized marijuana manufacturers allowed to supply researchers.[24] Changes to the legality of medical marijuana at the federal level are moving at a much slower pace than under state law. Even if physicians and patients in Florida operate in compliance with Florida law, they remain subject to enforcement under federal law.

For now, to ensure compliance with Florida law when ordering low-THC cannabis or medical cannabis for qualified patients, qualified Florida physicians should look to the Cannabis Act and the RTTA, along with Chapter 64-4, of the Florida Administrative Code and any additional regulations that may be enacted. Florida physicians should also keep an eye on the outcome of the impending vote on Amendment 2 in November, which has potential to change the framework of Florida's current medical marijuana law and lead to the creation of additional legislation.

Endnotes

1. This article is published for general information purposes only. It does not constitute legal advice and does not necessarily reflect the opinions of the firm or any of its attorneys or clients. The information contained herein may or may not be correct, complete or current at the time of reading. The content is not to be used or relied upon as a substitute for legal advice or opinions. No reader should act or refrain from acting on the basis of the content of this article without seeking appropriate legal advice. This article does not create or constitute an attorney-client relation-

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3. Under Florida law, "medical cannabis" is defined as all parts of any plant of the genus Cannabis, whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture or preparation of the plant or its seeds or resin that is dispensed only from a dispensing organization for medical use by an eligible patient as defined in Sections 499.0295 and 381.986(1), Florida Statutes. Florida law defines "low-THC" cannabis as a plant of the genus Cannabis, the dried flowers of which contain 0.8 percent or less of tetrahydrocannabinol and more than 10 percent cannabidiol weight for weight; the seeds thereof; the resin extracted from any part of such plant; or any compound, manufacture, salt, derivative, mixture, or preparation of such plant or its seeds or resin that is dispensed only from a dispensing organization. Fla. Stat. § 381.986(1).

4. Patient must be a Florida resident. *See* Fla. Stat. § 381.986.

5. Codified in Fla. Stat. § 381.986.

6. *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). This article does not address the legality of medical marijuana related businesses or enterprises.

7. The specific strain of low-THC cannabis is also known as "Charlotte's Web," after Charlotte Figi, a young girl suffering from Dravet Syndrome.

8. Codified in Fla. Stat. § 499.0295.

9. *See* endnote 3 for complete definition of low-THC cannabis.

10. *See* endnote 3 for complete definition of medical cannabis.

11. Fla. Stat. 499.0295(b) (2016).

12. Fla. Stat. 499.0295 (2016).

13. Fla. Stat. § 381.986(4)(a).

14. A list of the physicians who have completed the Low-THC and Medical cannabis Continuing Medical Education course is available at http://www.floridahealth.gov/programs-and-services/office-of-compassionate-use/resources/index.html (accessed on Sept. 17, 2016).

15. Fla. Stat. § 381.986(3)(a)-(b)(2016).

16. Cannabis delivery device means an object used, intended for use, or designed for use in preparing, storing, ingesting, inhaling, or otherwise introducing low-THC cannabis or medical cannabis into the human body. *See* Fla. Stat. § 381.986 (2016).

17. Pursuant to Florida Administrative Code Rule 64-4.009(1), ordering physicians that have satisfied the education requirements, may access the compassionate use registry using their existing FDOH Medical Quality Assurance Services credentials.

18. Information about the Office of Compassionate Use is available at http://www.floridahealth.gov/programs-and-services/office-of-compassionate-use/.

19. The Final Rule is found at Chapter 64-4, of the Florida Administrative Code.

20. For the official petition form for the current proposed Amendment 2, see *Constitutional Amendment Petition Form*, FLA. DEP'T OF ST., *available at* http://dos.elections.myflorida.com/initiatives/initdetail.asp?account=50438&seqnum=3 (last approved).

21. In 2014 the Florida Bar Board of Governors adopted a policy that the Bar will not prosecute Florida Bar members who advise a client regarding the validity, scope and meaning of the Florida laws regarding medical marijuana or for assisting a client in conduct the lawyer reasonably believes to be permitted by the laws of the State, so long as the lawyer also advises their client as to federal law and policies.

22. *See* Bruce E. Reinhart, Up in Smoke or Down in Flames? 90 MAR Fla. B.J. 20, 23-24 (March 2016).

23. *DEA Announces Actions Related to Marijuana and Industrial Hemp*; DEA Headquarters News (Aug. 11, 2016), https://www.dea.gov/divisions/hq/2016/hq081116.shtml (accessed Sept. 20, 2016).

24. *Id.*

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goods or services provided; and (2) the defendant knowingly failed to disclose noncompliance with a material statutory, regulatory, or contractual requirement rendering those representations misleading.[9]

Liability does not turn on whether the requirements were expressly designated as "conditions of payment."[10] Not only is liability not limited to violations of designated conditions of payment,[11] the Court also held that not all conditions of payments are automatically material.[12] Instead, whether a provision is labeled a condition of payment is relevant to but not dispositive of the materiality requirement.[13]

So What Does Materiality Mean?

The Court did not provide a bright line test but it did make clear that materiality is demanding.[14] The FCA is not "an all-purpose antifraud statute, or a vehicle for punishing garden-variety breaches of contract or regulatory violations."[15] It explained that a misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be *material* to the government's payment decision to be actionable under the FCA.

Section 3729(b)(4) of the FCA defines materiality as follows: "The term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property."[16] That definition has its roots in Supreme Court precedent under criminal fraud statutes.[17] Notably, the Court rejected a loose interpretation of that standard offered by the relator and the government, essentially that any violation that *could* affect a payment decision.[18] Instead, the Court characterized that standard as consistent with "rigorous" and "demanding" materiality standards long applied to limit fraud claims at common law.[19] The Court explained that the standard necessary to establish materiality would be whether the government *would* deny payment if it knew of the violation, and bringing the FCA's scienter element to bear, whether the defendant knew (or recklessly disregarded) the fact that it would.[20]

The Court offered guidelines for applying the FCA's rigorous materiality requirement.[21] Specifically, the Court found that the following are *not* sufficient alone to establish materiality:

- Where the government has the option to decline to pay if it knew of the defendant's non-compliance,
- Where noncompliance is minor or insubstantial, or
- Where the government merely designates compliance with a particular requirement as a condition of payment (though relevant).[22]

The following factors *could* be relevant to establishing materiality:

- The government's decision to expressly identify to the defendant that compliance a provision as a condition of payment (although not dispositive); or
- Evidence that the defendant knows that the government consistently refuses to pay claims based on

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noncompliance with the particular statutory, regulatory, or contractual requirement.[23]

The following type of information would be "strong evidence" that compliance is *not* material:

- If the government pays a particular claim in full despite its actual knowledge that certain requirements were violated. In fact, this would be considered "very strong" evidence, or
- If the government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position.[24]

In its conclusion, the Court affirmatively rejected the government's and First Circuit's "extraordinarily expansive view of liability."[25] It further asserted that "concerns about fair notice and open-end liability 'can be effectively addressed through strict enforcement of the Act's [rigorous] materiality and scienter requirements.'"[26] Finally, the Court reiterates that the FCA "is not a means of imposing treble damages and other penalties for insignificant regulatory or contractual violations."[27]

This case affirms the validity of the implied certification theory in certain circumstances. But without a bright light rule, the application of *Escobar* will be shaped by its interpretation by lower courts in FCA decisions to come.

Endnotes

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2. *Universal Health Services, Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1993 (2016).

3. *See U.S. ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1217-18 (10th Cir. 2008).

4. *See United States v. Sanford-Brown, Ltd.*, 788 F.3d 696, 711-12 (7th Cir. 2015); *see Escobar*, 136 S. Ct. at 1998.

5. *See United States ex rel. Gage v. Davis S.R. Aviation, L.L.C.*, 623 F. App'x 622, 625 (5th Cir. 2015) ("[T]his court has avoided deciding whether to recognize the implied certification theory.").

6. *See United States v. Sci. Applications Int'l Corp.*, 626 F.3d 1257, 1269 (D.C. Cir. 2010) (non-compliance with contract terms may give rise to false or fraudulent claims, even if the contract does not specify that compliance with the contract term is a condition of payment); *United States v. Triple Canopy, Inc.*, 775 F.3d 628, 636 (4th Cir. 2015) (same).

7. *See, e.g.*, *Mikes v. Straus*, 274 F.3d 687, 700 (2d Cir. 2001) ("[I]mplied false certification is appropriately applied only when the underlying statute or regulation upon which the plaintiff relies expressly states the provider must comply in order to be paid."); *Bishop v. Wells Fargo & Co.*, 823 F.3d 35, 48 (2d Cir. 2016) (extending the "express statement" requirement of *Mikes* beyond FCA claims premised on healthcare fraud); *Escobar*, 136 S. Ct. at 1998.

8. Transcript of Oral Argument at 18:4-10, *Escobar*, 136 S. Ct. 1989 (2016) (No. 15-7), https://www.supremecourt.gov/oral_arguments/argument_transcripts/15-7_6537.pdf.

9. *Escobar*, 136 S. Ct. at 1995-1996.

10. *Id.* at 1996.

11. *Id.* at 2001.

12. *Id.*

13. *Id.*

14. *Id.* at 2003.

15. *Id.* (internal quotation and citation omitted).

16. *Id.* at 2002.

17. *Id.* (citing *Neder v. United States*, 527 U.S. 1, 22 (1999)).

18. *Id.* at 2004.

19. *Id.* at 2003, 2004 n.6.

20. *Id.* at 2002-2003.

21. *Id.*

22. *Id.* at 2003-2004.

23. *Id.*

24. *Id.*

25. *Id.* at 2004. The Court vacated the judgment of the Court of Appeals and remanded the case for reconsideration of whether respondents sufficiently pleaded a FCA violation. *Id.*

26. *Id.* at 2002 (quoting *Sci. Applications Int'l Corp.*, 626 F.3d at 1268).

27. *Id.* at 2004.

The Implications of MACRA on Physician Compensation and Employment

By: Gerald M. Del Amo[1]

The Medicare Access to Care and CHIP Reauthorization Act of 2015 (MACRA) will have an historic effect on physician compensation. That is, after all, its stated purpose and intent—to transform physician payments from a system that is based on volume to one that is based on value. Beyond that though, it is becoming evident that MACRA will also have a profound impact on, and serve as a catalyst for, physician-hospital consolidation. Indeed, because MACRA gives rise to the need for significant investments in information technology infrastructure, as well as the dedicated resources to implement, manage, and oversee it, MACRA is expected to further drive physician-hospital alignment.

As physicians in solo and small practices confront their new obligations and grow frustrated with the onerous demands MACRA will impose on them, health systems will look to position themselves as secure landing spots for such physicians. And while such entities may be better situated to adjust and adapt to the new MACRA requirements, they too will look to create and design new physician payment models and methodologies to conform with the new payment system requirements.

The purpose of this article is to provide an overview of MACRA's changes, discuss its expected impact on the current state of physician practices, and explore some of the possible outcomes with respect to hospital physician employment.

What is MACRA?

On April 27, 2016, the Centers for Medicare and Medicaid Services (CMS) unveiled its proposal to implement physician payment reforms required by the Medicare Access to Care and CHIP Reauthorization Act of 2015 (MACRA),[2] bipartisan legislation that replaced the Sustainable Growth Rate (SGR) formula with a new approach to compensating physicians under Medicare. The Notice of Proposed Rulemaking is expansive, covering over four hundred pages in the Federal Register.[3]

According to CMS, MACRA looks to advance a "forward-looking, coordinated framework for health care providers to successfully take part in the CMS Quality Payment Program that rewards value and outcomes."[4] Once implemented, the reforms will have a major impact on physician compensation by establishing a direct, quantifiable connection between compensation and performance. Specifically, MACRA will impose an obligation on most physicians[5] to choose whether to: (1) be evaluated and compensated based on performance measures under the Merit-based Incentive Payment System (MIPS) or, (2) participate in an Advanced Alternative Payment Model (APM). This article will focus on the former, MIPS, which will tie Medicare's physician payments to a performance score made up of four separate categories.

The four performance categories in MIPS are: (1) Quality measurement (based on the former Physician Quality Reporting System or PQRS); (2) Resource use (using cost measures currently used in the value-based payment modifier (VM) program); (3) Clinical practice improvement activities (activities such as population management, practice access, and patient safety); and (4) Advancing care information (based on the criteria for meaningful use of electronic health record (EHR) technology).[6]

Each of the four categories will be scored based on information provided by the physician, with each comprising a relative percentage toward a composite score.[7] The composite score will then be compared against a threshold score that CMS will establish every year based on the data reported from the prior year, and if the composite score is above the threshold, a positive adjustment will be applied to the physician's payments; but if the composite score is below the threshold, then a negative adjustment will be applied.[8] The amounts at stake are set to gradually increase, from a low of four percent (4%) in 2019 to a high of nine percent (9%) in 2022.[9]

MACRA will apply to payments beginning on January 1, 2019.[10] However, the measurement period for 2019 will begin on January 1, 2017.[11] According to a September 8, 2016 Announcement by the CMS Acting Administrator, Andy Slavitt, CMS will allow physicians to pick their pace of participation for that first performance period—during 2017, eligible physicians and other clinicians will have multiple options for participation. Per CMS, "choosing one of these options would ensure [physicians] do not receive a negative payment adjustment in 2019."[12] These options and other supporting details will be described fully in the final rule, which is expected to be released by November 1, 2016.

Who will be most affected?

CMS estimates that under MACRA's requirements, MIPS will distribute payment adjustments to between approximately 687,000 and 746,000 eligible clinicians in 2019.[13] The adjustments would be approximately equally distributed between negative adjustments ($833 million) and positive adjustments ($833 million) to MIPS eligible clinicians, to ensure budget neutrality.[14] But when one looks at the nature of the physician practices CMS expects to be affected, there is a clear trend—the smaller the practice, the more likely the expected adjustment under MACRA will be negative:[15]

Practice Size	Eligible Clinicians	Expected negative adjustment
Solo	102,788	87%
2-9	123,695	69.9%
10-24	81,207	59.4%
25-99	147,976	44.9%
100+	305,676	18.3%

The expectation is that physician groups will need to be of a certain size in order to be able to adapt to the resource-heavy commitments for information technology and infrastructure necessary to support the data reporting required by MIPS.

In a recent survey by the Deloitte Center for Health Solutions, a surprising fifty percent (50%) of physicians said they have never heard of MACRA, while another thirty-two percent (32%) recognize it by name but are not familiar with its requirements.[16] The same survey found that fifty-eight percent (58%)

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of physicians say they would opt to be part of a larger organization to reduce individual increased financial risk and have access to supporting resources and capabilities.[17]

As a result, one can anticipate that physicians, especially those in smaller groups, will be looking to align themselves with bigger practices, or health systems, in order to avoid being negatively impacted by the new reimbursement model. Some physicians might choose to limit their Medicare patients or even opt out of Medicare altogether. But more likely, MACRA will serve as a further catalyst to physicians seeking employment from health systems. In order to capitalize, the successful hospital systems will need to have robust employment models.

The Evolving Physician Employment Landscape

The earliest forms of hospital physician employment agreements compensated physicians using a flat salary. In an effort to incentivize physicians to remain productive and increase their productivity, health systems began to shift to employed physician compensation models which took into account a physician's volume or productivity, often relying on measures like work relative value units ("WRVU") or revenues/collections derived from personally-performed services.[18]

There are so-called "straight productivity" models, where every WRVU a physician performs is paid at a predetermined WRVU rate. For example, if a physician whose contract provides for a compensation rate of $60 per WRVU performs 5,000 WRVUs, the physician will receive compensation of $300,000.00. If the physician's colleague, who has the same contract but works more hours and is more productive, performs 10,000 WRVUs, the physician's colleague will receive $600,000.00 in compensation.

There are also productivity models which set forth a baseline or threshold WRVU target and a bonus or incentive payment if the threshold is exceeded. For example, a physician receives a base salary of $300,000.00 with an annual WRVU target of 5,000. If the physician exceeds 5,000 WRVUs, the physician will earn a productivity "bonus" of $60 for every WRVU above 5,000. But if the physician performs less than 5,000 WRVUs, then the physician's base salary may either be re-evaluated or decreased (perhaps by an amount equal to the difference between the WRVU target and the WRVUs produced times $60). In both of the aforementioned employed physician contract models, physicians are incentivized to be productive because their compensation is directly tied to their productivity.

More recently, employed physician compensation has begun to factor in a new element—quality. The movement has been spurred at least in part by The Affordable Care Act ("ACA") and CMS' goal of transitioning from fee-for-service payment to value-based payment systems. To that end, Medicare began measuring the value and quality of care provided by physicians through several patchwork programs, e.g., PQRS and the Medicare EHR Incentive Program. However, under these programs, bonus compensation and penalties are generally tied to the act of reporting itself, and not to the substance of what is being reported. This changes dramatically under MACRA, which takes a gigantic leap forward and ties payment to performance relative to peers.

Given the current landscape and the imminent changes, physician employment models based primarily on productivity are now lagging behind payer reimbursement changes like MACRA. And so, in order to prevent MACRA's negative physician compensation adjustments from crippling their bottom lines, health systems will endeavor to revise their employed physician compensation models. It will no longer be an option to not measure or factor in quality.

Ideas for the Next Step of Physician Compensation

If MACRA is going to lead to an increase in physicians employed by health systems, and Medicare's payments to such physicians are going to become contingent on the physicians' achievement of certain quality metrics, then the next step for health systems is to include quality metrics as a component of physician compensation. Looking forward, health systems will have several options for incorporating quality, with different options depending on how much risk the health systems will want to take on for themselves.

Perhaps the most straightforward option is to tie a physician's base compensation to the physician's MIPS composite score. Health systems might include a provision in their employment agreements mandating the employed physician's compliance with the MIPS reporting requirements, along with a corresponding provision linking the physician's base compensation to the physician's composite score—a negative MIPS composite score results in a decrease to base compensation of a pre-determined amount, while a positive MIPS composite score results in an increase to base compensation of a predetermined amount. In this scenario, the predetermined increase or decrease can mirror the gradual scale MACRA will implement (4% in 2017, 5% in 2018, and 9% in 2019 and beyond). Or, the health system can choose to exceed the amounts at stake, e.g., by setting the at-risk amount at 10% or 15%.

Another option is to make any bonus or incentive compensation contingent on receiving a positive MIPS composite score. For example, take a physician who is employed on a productivity model with a bonus payment due if a certain WRVU threshold is exceeded. The compensation might be structured so that the base is not directly affected by the MIPS performance, but failure to record a positive MIPS composite score will render the physician ineligible for a productivity bonus. The effect would be to incentivize quality as much as productivity, since a physician who generates a high-volume of WRVUs but does so without meeting the quality metrics would not be not rewarded for the high productivity. The compensation structures are destined to change, regardless of the methodology chosen.

Conclusion

In the proposed Final Rule, CMS described MACRA as "a milestone in efforts to improve and reform the health care system. Building off of the improvements to access under the Affordable Care Act, MACRA puts an increased focus on the quality and value of care delivered."[19] And by "incentivizing quality and value for eligible clinicians," CMS states it is "supporting the nation's progress toward achieving a patient-centered health care system that delivers better care, smarter spending, and healthier people and communities."[20]

But in its quest to tie compensation to quality, MACRA carries with it significant

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costs in the form of time, labor, and the physician practice infrastructure necessary to accurately capture, manage, and report the required data to CMS. The added costs are expected to drive even more physicians into employment with health systems, as the systems will be better suited to spread the costs and achieve economies of scale across their employed physician business units. Given these realities, health care systems will look to modernize their physician compensation structures to bring them in line with quality-based reimbursement models—those who do so quickly and seamlessly will be best positioned to emerge successfully in the post-MACRA world.

Endnotes

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2. Pub. L. 114-10, enacted April 16, 2015.
3. Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models; Proposed Rule, 81 Fed. Reg. 28161-28586 (May 9, 2016) (the "Proposed Rule").
4. *Id.* at 28165.
5. *Id.* at 28173-78. The Proposed Rule sets forth certain categories of clinicians who are excluded from the obligations of MACRA, e.g., non-patient facing clinicians, new Medicare enrolled clinicians, and clinicians whose Medicare volume is below a specified threshold.
6. *Id.* at 28182.
7. *Id.* at 28164 and 28268.
8. *Id.*
9. *Id.* at 28273.
10. *Id.* at 28163.
11. *Id.*
12. Slavitt, Andy, *Plans for the Quality Payment Program in 2017: Pick Your Pace*, The CMS Blog (September 8, 2016). Available at https://blog.cms.gov/2016/09/08/QualityPaymentProgram-PickYourPace/.
13. The Proposed Rule, 81 Fed. Reg. 89 at 28165.
14. *Id.*
15. *Id.* at 28375 (Table 64).
16. Mitch Morris, Anne Phelps, Wendy Gerhardt, and Natasha Elsner, *Are Physicians Ready for MACRA and its Changes? Perspectives from the Deloitte Center for Health Solutions 2016 Survey of US Physicians* (2016), available at: http://edit.modernhealthcare.com/assets/pdf/CH106774829.PDF.
17. *Id.*
18. Bowers, Jan, *The Different Ways Hospitals Pay*, ACP Hospitalist (October 2010), available at: http://www.acphospitalist.org/archives/2010/10/money.htm.
19. The Proposed Rule, 81 Fed. Reg. at 28165-66.
20. *Id.*