



GEORGIA HEALTH LAW DEVELOPMENTS

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NOTICE

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MESSAGE FROM THE CHAIR

Greetings Health Law Section Members,

The State Bar of Georgia Health Law Section Executive Committee has been busy planning our upcoming Advanced Health Care Law ICLE on October 17, 2014, at The Four Seasons in Atlanta. We are excited about the upcoming program which features some of Georgia's finest health care lawyers.

We would like to thank all of the authors who contributed to this edition of the Health Law Section Newsletter. In this most recent edition, Lyn Garson provides insight in dealing with attorneys with mental health and substance abuse issues. Also, Thomas Hawk and Kerrie Howze provide an update on the Composite Medical Board's new standards for practitioners treating patients via tele-medicine. Former Assistant United States Attorney Scott Grubman has also contributed an update on Stark's Self-Referral Prohibitions and Medicaid Claims. Thomas Baker has also contributed an article on the Medicare Shared Savings Program. Finally, we appreciate the contribution from Eric Swartz regarding payments under the Medicare and Medicaid Electronic Health Record Incentive Programs. We also would like to thank Dan Mohan for his assistance editing and publishing the newsletter.

The Executive Committee strives to prepare meaningful, substantive programs for our section and provide you with information relevant to the practice of health care. We invite members to submit articles, reports, and proposals for presentations that would be informative to the membership.

It has been an honor to serve as Chair of the Section in 2014. I am grateful for the contributions of the members of the State Bar of Georgia Health Law Section in helping make this such a great year.

Best regards,

Brian F. McEvoy
Chair, Health Law Section

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It's Time to Talk About It

Lawyers with Mental Health and Substance Abuse Issues

By Lyn S. Garson
McKenna Long & Aldridge LLP

The legal profession has a problem. We are just starting to talk openly about it, which is good. We don't have the habit of doing that and many lawyers are resistant, which is not so good.

I am talking about mental health and substance abuse issues. Do you think that we as a profession are open to discussing such problems or approaching them with compassion? I think not. I was told anecdotally by the director of a foundation whose mission is to help lawyers and law students that she got the following response from the dean of a prominent law school when she asked to come on campus to make a presentation: "We don't have any depressed students here. But I'm retiring soon, so come back next year and maybe you'll have better luck." I will be speaking at a webinar soon with Kathy Flaherty, a Connecticut lawyer, who is a Harvard graduate and was appointed to the Sandy Hook Commission last year – not too shabby. She also happens to live with bipolar disorder. After disclosing her mental illness on Connecticut's fitness application, she was denied admission, put through a wringer of appeals and ultimately granted conditional admission, which required her to provide a doctor's report and affidavit semiannually. The condition was not removed for nine years.

I don't think anyone would deny that these are tough issues to confront in any context. People who do not suffer from mental health or substance abuse issues often don't know what to say, how to say it, whether comments are offensive, and/or whether the person they are approaching is in denial or amenable to getting help. Notwithstanding any of those questions and concerns, it is time to stop sweeping these issues under the rug. It is encouraging that the American Bar Association has recognized that these are topics whose time has come by embarking on a study with the Hazelden Betty Ford Foundation to survey the current rates of substance use, depression and anxiety among U.S. lawyers. The Director of the Foundation's Legal Professionals Program notes that: "Available estimates peg the addiction rate of attorneys to be roughly twice that of the general population. Those estimates are quite dated though, and it appears the problem may be growing even worse."

In Georgia, we have our fair share of problems. I personally know lawyers who are on leave for mental health issues. I also know lawyers who are alcoholics and drug addicts. I myself have what is currently referred to as "lived experience." I suffered from depression through all of my legal career and voluntarily hospitalized myself three times

between 2000 and 2010 for issues ranging from binge eating disorder to depression to anxiety to bipolar to substance abuse. I joke that if you want to talk to someone about your issues, come to me – it's one stop shopping, since I can cover most of the mental health spectrum and substance abuse. (For those of you who are not familiar with the concept, binge eating disorder is an addiction like alcoholism or drug addiction, with food being the alcohol or drug.) More and more in Georgia we are also being faced with the worst result of all, lawyer suicides. In the past two and a half years, we have lost at least five lawyers to suicide.

Important efforts are being made to confront these issues in the legal community in Georgia. If you have attended a CLE seminar in the past year, you have seen the video that is a mandatory part of every session. The video presents two Georgia lawyers, both of whom have been personally touched by suicide, in one case a husband and in the other a son. The video describes the warning signs of depression and what steps colleagues should take when there are concerns of a potential suicide. It may be viewed at http://www.gabar.org/committeesprogramssections/programs/ap/suicide_awareness.cfm.

The Bar's Lawyer Assistance Program, which offers confidential help and treatment, is described in the video. This program, known as the "LAP" is a critical piece of what is available to help our legal community. LAP offers a confidential telephone hotline (800-327-9631) and up to six prepaid in-person counseling sessions with a licensed counselor per year. Anonymous interventions can be made, so that if you are worried about a colleague, you can call the hotline and a staffer will reach out to the struggling attorney with an offer for help, without identifying you as the source. Details are available at <http://www.gabar.org/committeesprogramssections/programs/ap/>. Many employers have employee assistance programs and, as part of those programs, wellness initiatives that tie into and supplement the LAP offerings.

The Georgia Bar has a suicide prevention and awareness committee that is just getting underway. Headed by Robin Frazer Clark, immediate past president of the Georgia Bar Association, the committee was originally constituted in the wake of three lawyer suicides in Georgia during a nine month span in 2012-13. Ms. Clark was discussing her "How to Save a Life" initiative with the Bar's executive director on the same day that federal assistant public

defender Thomas “Jake” Waldrop took his life in the Bar’s parking garage.

The State Bar is also developing a peer counseling program. This is an effort to establish a statewide network of volunteer attorneys who are willing to help others. Once selection procedures, some protocols and a training session are finalized, the program will commence. Other states (e.g., New York, North Carolina, Louisiana, Illinois, Colorado) have benefited from such efforts and it will be an excellent addition to our resources in Georgia.

Here’s the rub. In Georgia, it has been estimated that LAP is used to one percent (1%) of its capacity. How many of you have ever heard of it, much less used the services that are offered? How many of you have faith that if you disclosed your issues or those of another in your firm (or corporation, law school, judicial or other setting), that there would not be negative career consequences? When I first applied for my job at McKenna Long and Aldridge, I was so terrified that I would have to reveal my previous mental health history that I almost didn’t apply for health insurance. I was advised by colleagues from previous jobs not to disclose my history, despite the protection of the Americans with Disabilities Act and the privacy barrier that is supposed to exist between the Human Resources/Benefits side of a business and the business side itself. I was ready and willing to follow their advice, and in fact did so to an extent, giving up the unlimited care option of long term care insurance in favor of a term policy that didn’t require the disclosures.

I went to work at McKenna Long & Aldridge in June 2011 and kept my head down for a year. By the time I was ready to disclose my issues a year later, I had a solid twelve months under my belt of friendly relations with my colleagues and a record of good performance. My reasons for disclosure were unusual – I had written a memoir about my journey from pre-suicidal-depressed-out of work-down-trodden dependent to by and large thriving-practicing-stable attorney. I had every intention of publishing my book and no desire to do so under a pseudonym. One summer day in 2012 I told all of the members of my department about the book, showing them the cover that bore the same name as my daily emails to clients. They were to a person supportive, which speaks volumes about them and also provides a lesson about avenues for change. If we weren’t systemically so confined by fear of negative repercussions from candor, there might be more room for disclosure and dialogue. One thing I know – as long as mental health and substance abuse issues are hidden away as deep, dark secrets, people who suffer will not get help, firms will lose productive workers for the longer rather than the shorter term and progress will not be made on any front.

Let’s turn that around and take some steps toward a culture of openness, compassion and productivity. How can we do this in Georgia? Hold some educational sessions in-house on mental wellness and treatment for substance abuse. Call in the LAP for an information session on what they can do for you and members of the firm. Raise awareness about the LAP. This won’t take much, just an email and follow-up reminders. When the peer counseling initiative gets going, spread the word and encourage colleagues to sign up. Let the Bar know that you would like the video on lawyer suicides to continue to be shown at CLE presentations (the current mandate was for one year only, which will expire shortly.) Talk to your clients about a culture of openness and compassion. Pave the way for them to be on board before there is an issue, so that when an attorney goes out on mental health FMLA or to rehab, the client is prepared and accepting.

Does that last suggestion seem unrealistic? It is not. I took such a chance just last month. I had developed a close working relationship with a client representative, on whose matters I spend a good bit of my time. I had occasion to drive the client to the airport after a closing and, as we talked, the topic turned to life challenges that we had overcome. I had a copy of my memoir in the trunk, and in the few minutes before I dropped my client off, I had to decide whether to give the book to her or to continue to keep our relationship at arms’ length. I didn’t know if such a natural opening would ever come again, and I decided “nothing ventured, nothing gained,” so I gave her the book to take on vacation with her.

Over the next week, I became convinced that I had made a mistake and that best case scenario from now on would be a cordial but stiff working relationship. Worst case scenario would be a firestorm that would pervade the client’s offices, leap to the firm and put my job in jeopardy. The client’s first email to me back from vacation confirmed my fears – formal, all business. I couldn’t sleep that night. A week or two went by and we had a few exchanges, some humorous, and I started to feel cautiously optimistic that this was going to turn out okay. Then I received the following message from my client: “Loved your book. You are an amazing person and I am fortunate to know you. Can’t wait for the play.” Reading that was one of the finer moments in my life. And it gives me hope that as a profession we can shift our culture to embrace the idea that openness, collaboration and cooperation are the way to go when addressing mental health and substance abuse issues among our colleagues. We have worked through similar issues before (e.g., maternity leave in the 1980’s) and we can do it now. The first step, wherever you practice, is to start the conversation.

Composite Medical Board Enacts New Standards for Practitioners Treating Georgia Patients Via Telemedicine

By Thomas H. Hawk, III and Kerrie S. Howze
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Technology is rapidly changing the delivery of healthcare services. For instance, just recently we have seen the introduction of smartphone apps and other devices that purport to have certain health monitoring capabilities. But as healthcare technology evolves, so must the law to ensure appropriate protections are in place for consumers of those technologies. In Georgia, the Composite Medical Board (the “Board”) recently adopted new regulatory requirements governing physicians, physician assistants (“PAs”) or advanced practice registered nurses (“APRNs” and collectively, “practitioners”) wishing to provide services to Georgia patients through “electronic or other such means” (i.e., via what is commonly referred to as “telemedicine”). Chief among them is a mandate that practitioners must have either personally seen, or have received a referral from another practitioner who has personally seen, the patient the practitioner wishes to treat via telemedicine unless certain exceptions are met. This “in-person” requirement is just one of several standards that must be satisfied under the new rule, 360-3-.07, “Practice Through Electronic or Other Such Means,” or risk facing disciplinary action by the Board.¹

Dr. Jean Sumner, the Board’s current Medical Director, recently stated that “A lot of companies say they are practicing telemedicine, but there need to be standards in place. Georgia has always been one of the leaders in telemedicine, but we want to make sure that, as healthcare delivery evolves -- and technology evolves -- Georgians are protected.”

Indeed, Georgia has a near decade-long history of supporting care delivery via telemedicine. In late 2004, former Insurance and Fire Safety Commissioner John Oxendine announced the “Georgia Rural Health Initiative,” which included a three-year, \$11.5 million commitment from WellPoint, Inc. to establish, equip and finance 36 telemedicine centers throughout the state plus four academic teaching hospitals.² The following year, the Georgia legislature enacted the Georgia Telemedicine Act to “mitigate geographic discrimination in the delivery of health care by recognizing the application of and payment for covered medical care provided by means of telemedicine.”³

To continue the momentum, the Georgia Partnership for Telehealth was formed at the end of Wellpoint’s three-year commitment to build on the success of the telemedicine program established under the Rural Health Initiative.⁴ Based in Waycross, Georgia, the Georgia Partnership for Telehealth is a subscriber-based model, wherein the Partnership provides subscribing physicians or sites technical assistance in setting up equipment and infrastructure necessary to connect to the

Partnership’s Open Access Network; comprehensive support services, including scheduling, credentialing and program coordination; ongoing education and training; 24-hour technical support; and a liaison to provide ongoing program support. Today there are approximately 600 rural and specialty sites operating within the network, including over 200 specialists representing 36 different specialties. In 2013, there were over 130,000 encounters through the network, including specialty encounters for wound care, psychiatry, neurology (stroke), pediatric endocrinology, dermatology, OB/GYN (high risk pregnancy) and cardiology, and the Partnership is projecting over 200,000 encounters for 2014.

Thus, the momentum for telemedicine services appears to be gaining, and the Board does not see this new rule as any hindrance to continued progress in that direction.

Key Provisions of the Rule.

1. Licensure.

The new rule requires, first and foremost, that “[a]ll treatment and/or consultations must be done by Georgia licensed practitioners.”⁵ Georgia generally has required licensure for telemedicine practitioners since 1997 under the Medical Practice Act,⁶ though that provision technically addressed licensure of only those persons providing telemedicine services to Georgia patients from a location outside of the state. The rationale for this licensure requirement is rather straightforward – if a practitioner providing telemedicine services is not licensed by the Board, then the Board has no authority to take disciplinary action against the practitioner or otherwise regulate the standard of care provided.

Note that a number of other states, such as Mississippi and North Carolina, have also adopted the full licensure requirement.⁷ Other states, however, have taken different approaches that stop short of full licensure. For example, some states, such as Alabama and Tennessee, have created a special category of licensure for telemedicine practitioners.⁸

2. The “In-Person” Requirement.

Under the new rule, a Georgia licensed physician, PA or APRN must have either “personally seen and examined the patient and [be] provid[ing] ongoing or intermittent care by electronic or other such means” or be “providing medical care by electronic or other such means at the request of a physician, physician assistant or advanced practice registered nurse who

has personally seen or examined the patient,” unless certain exceptions are met.⁹ The first exception allows for a practitioner to provide treatment via telemedicine services based on a request from a Public Health Nurse, Public School Nurse, the Department of Family and Children’s Services, law enforcement or community health or child advocacy centers, but only to the extent that the practitioner can examine the patient using “technology and peripherals that are equal or superior to an examination done personally by a provider within that provider’s standard of care.”¹⁰ The Board added this exception in response to specific comments that permitting referrals only from physicians, PAs and APRNs who had personally seen and examined the patient would not permit the continued practice of consultations at the request of law enforcement or child protective services personnel to assist in cases involving suspected child abuse or sexual assault.

The second exception – which permits a Georgia licensed practitioner to treat a patient via telemedicine regardless of the referral sources so long as the practitioner is able to examine the patient via technology equal or superior to that that would be possible if done in person – arguably encompasses the first.¹¹ The language in this exception reads identically to the latter part of the language in the first exception – i.e., it permits a practitioner to provide telemedicine services without having either personally seen the patient or receiving a referral from another practitioner who has personally seen the patient if the telemedicine practitioner “is able to examine the patient using technology and peripherals that are equal or superior to an examination done personally by a provider within that provider’s standard of care.” As a practical matter, both exceptions may remain in the final rule as a matter of timing – the Board incorporated the first exception for referrals from law enforcement and child protective services prior to adopting the second exception, which would permit treatment via telemedicine regardless of the referral source so long as the telemedicine practitioner could perform an equal or superior examination using telemedicine technology.

Practically, this exception could come into play when a practitioner’s standard of practice would not typically require a “hands on” examination, such as in the case of certain psychiatric examinations, but it also specifically recognizes the advancement of technology that could be used by a practitioner remotely to inform his or her clinical decisionmaking just as efficiently – if not more so – than would be the case during an in-person examination. For example, a telemedicine practitioner could conduct a standard history and physical using devices that would allow the telemedicine practitioner to listen to the patient’s heartbeat and visually examine other parts of the body, such as the inside of the patient’s mouth or ear. But whether the examination by peripheral devices rises to the level of being “equal” or “superior to” an in-person examination likely will require a case-by-case determination depending on the patient and applicable standard of practice.

Notably, an earlier version of the rule included a separate provision that would have required a physician to have personally seen a patient or have provided the initial consultation or treatment via telemedicine before a PA or APRN could provide treatment via telemedicine. The Board modified this provision in the final rule to require that the physician document that the provision of care by telemedicine is within the physician’s scope of practice, and that the nurse practitioner or PA to whom the physician delegates the provision of those services has demonstrated competence in the provision of care via telemedicine.¹² Thus, the intent of this provision is really to ensure that any physician delegating the provision of telemedicine services is himself or herself appropriately qualified and capable of providing telemedicine services before delegating to an extender – not to discriminate against appropriately qualified PAs or nurse practitioners. The new language accomplishes that goal without requiring that the delegating or supervising physician personally have conducted the first in-person or telemedicine visit.

Another related, but separate, provision of the rule requires that the physician, PA or nurse practitioner providing care via telemedicine “make diligent efforts to have the patient seen and examined in person by a Georgia licensed physician, physician assistant or nurse practitioner at least annually.”¹³ Though practically the Board may be most likely to discover non-compliance in the case of a patient complaint related to his or her treatment via telemedicine rather than any ongoing monitoring, the provision suggests a belief by the Board that telemedicine should not necessarily be a permanent treatment option.

3. Patient History.

Another key provision of the rule requires that a “history of the patient...be available to the Georgia licensed physician, [PA] or [APRN] who is providing treatment or consultation via electronic or other such means.”¹⁴ Presumably, this provision is designed to work in conjunction with the provision under the regulation defining “unprofessional conduct,” which states it is unprofessional conduct to “provid[e] treatment via electronic or other means unless a history and physical examination has been performed by a Georgia licensee,” exclusive of situations involving call coverage for another physician or an attending physician obtaining consultations or recommendations from other physicians.¹⁵ Practically, it seems it would be difficult for the Board to police compliance with this provision, though the Board clearly has disciplinary authority in the event of violation. In many instances, however, the physician likely would be capable of requesting the patient’s history from the referring physician, or the physician himself or herself would be capable of performing a history and physical examination during the initial telemedicine visit using peripheral devices that could satisfy the regulatory requirements.

4. Controlled Substances.

With respect to controlled substances, section (c) of the rule expressly states that the rule does not authorize the prescription of controlled substances for the treatment of pain by electronic or other such means.¹⁶ This provision generally is intended to prevent “virtual pain clinics,” or the prescribing of pain medications without any sort of physical evaluation. A separate rule – 360-3-.06 – sets forth the minimum standards for prescribing controlled substances for the treatment of pain and chronic pain, which, among other things, includes a requirement that a physical examination of the patient have been conducted.

5. Other Requirements.

The new telemedicine rule contains a number of other requirements designed to protect Georgia patients, such as the requirement that the patient “be given the name, credentials and emergency contact information for the Georgia licensed physician, [PA] and/or [APRN] providing treatment or consultation,” and “be provided with clear, appropriate, accurate instructions on follow-up in the event of needed emergent care related to treatment.”¹⁷ As articulated by Dr. Sumner, the Board’s rationale for including those provisions is pretty simple – patients simply have a right to know who they are seeing, and should know what to do in the event of an emergent situation following the provision of telemedicine care.

The rule also explicitly states that practitioners providing services via telemedicine are held to the same standard of care as licensees employing more traditional, in-person medical care, and that nothing in the rule excuses any practitioner from ordering appropriate laboratory or other diagnostic tests required to make diagnoses within the minimum standard of care. The American Telemedicine Association criticized a prior version of the rule containing these same provisions, however, stating that the rule creates “separate but unequal standards” for telemedicine providers versus traditional providers, and that the rule, in effect, thwarts the use of telemedicine under the guise of regulating medical practice.¹⁸ Nevertheless, others, such as the Medical Association of Georgia, fully support the rule and believe it strikes an appropriate balance between expanding access to healthcare services via innovative technology and providing appropriate protection for patients being treated via that technology.

The Future of Telemedicine in Georgia, and Beyond.

As technology continues to evolve, more avenues for the provision of telemedicine and telehealth services will likely become available. These new technologies have the potential to go beyond the reach of expanding access to healthcare in rural areas – which is perhaps the current focus – such as to delivering care in rural and inner city schools, prisons and even internationally. As the technologies grow and popularity of use spreads due to increased physician and

patient comfort levels, there undoubtedly will be future questions and issues that arise. The Georgia Board has been on the forefront of considering these emerging issues thus far and, therefore, likely will continue to closely monitor developments in this area and make any necessary changes governing the practice of medicine in Georgia to ensure continued patient safety.

¹ Ga. Comp. R. & Regs. 360-3-.07. The Board adopted the rule January 13, 2014, and it was effective February 2, 2014.

² See “Oxendine touts \$126.5 Rural Health Care Initiative,” Atlanta Business Chronicle (Nov. 30, 2004), available at <http://www.bizjournals.com/atlanta/stories/2004/11/29/daily17.html>.

³ O.C.G.A. § 33-24-56.4. Generally, this provision requires health insurers to reimburse services provided via telemedicine if those services would otherwise be covered under a health benefit policy if provided in person.

⁴ See Georgia Partnership for Telehealth, <http://www.gatelehealth.org/index.php/about/about-gpt/>.

⁵ Ga. Comp. R. & Regs. 360-3-.07(a)(1).

⁶ O.C.G.A. § 43-34-31. (“A person who is physically located in another state or foreign country and who, through the use of any means, including electronic, radiographic, or other means of telecommunication, through which medical information or data are transmitted, performs an act that is part of a patient care service located in this state, including but not limited to the initiation of imaging procedures or the preparation of pathological material for examination, and that would affect the diagnosis or treatment of the patient is engaged in the practice of medicine in this state. Any person who performs such acts through such means shall be required to have a license to practice medicine in this state and shall be subject to regulation by the board.”).

⁷ Miss. Code Ann. § 73-25-34; N.C. Gen. Stat. Ann. § 90.1.1(5) (defining the practice of medicine or surgery to include telemedicine); N.C. Gen. Stat. Ann. 90-18 (no practice without license); see also N.C. Medical Board position statement, available at http://www.ncmedboard.org/position_statements/detail/telemedicine.

⁸ Ala. Code Ann. § 34-24-500 et seq.; Tenn. Code Ann. § 63-6-209; Tenn. Comp. R. & Regs. 0880-2-.16. ; Tenn. Comp. R. & Regs. 1050-2-.17 (osteopaths).

⁹ Ga. Comp. R. & Regs. 360-3-.07(a)(3).

¹⁰ *Id.* at 360-3-.07(a)(3)(c).

¹¹ *Id.* at 360-3-.07(a)(3)(d).

¹² *Id.* at 360-3-.07(a)(5). The prior language read “When Georgia licensed physician assistants or advanced practice registered nurses are providing care by electronic or other such means, such physician assistants or advanced practice registered nurses may only do so after the supervising or delegating physicians have seen or examined the patient in person or have provided the initial treatment or consultation for the patient via electronic means.” See October 2012 proposed rule, available at http://medicalboard.georgia.gov/sites/medicalboard.georgia.gov/files/related_files/site_page/telem.pdf.

¹³ *Id.* at 360-3-.07(a)(8).

¹⁴ *Id.* at 360-3-.07(a)(2).

¹⁵ *Id.* at 360-3-.02(6).

¹⁶ *Id.* at 360-3-.07(c).

¹⁷ *Id.* at 360-3-.07(a)(6) & (a)(7).

¹⁸ See Letter from American Telemedicine Association to Carol Dorsey (Oct. 26, 2012), available at <http://www.americantelemed.org/docs/default-source/policy/ata-comments-on-georgia-medical-boards-anti-telemedicine-proposal.pdf?sfvrsn=6>.

Stark's Self-Referral Prohibitions and Medicaid Claims

By Scott R. Grubman
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On May 19, 2014, U.S. Representative Jim McDermott (D-WA) introduced legislation entitled the Medicaid Self-Referral Act.¹ That bill, which is currently pending in the House of Representative's Subcommittee on Health, would amend the Medicaid subchapter of the Social Security Act to prohibit payment for a Medicaid designated health service furnished to an individual on the basis of a physician's referral if the physician (or an immediate family member) has an ownership or investment interest or a compensation arrangement with the entity furnishing the service that would not comply with Medicare requirements.² In its current draft form, the bill would also provide that a claim for reimbursement for an item or service that violated the provisions of the proposed bill would constitute a false or fraudulent claim for purposes of the federal False Claims Act ("FCA").³ The express purpose of this legislation is to "apply the Medicare restriction on self-referral to State plan requirements under Medicaid."⁴ In plain terms, Representative McDermott's legislation would extend the Stark law's physician self-referral prohibition to Medicaid claims.

The fact that Representative McDermott saw a need to introduce such legislation raises an obvious, yet important, question: Does Stark's self-referral prohibition, in its current form, apply to Medicaid claims? The Department of Justice ("DOJ"), unsurprisingly, answers that question in the affirmative. This view has been accepted by at least two federal district courts in recent years. Yet, the Stark law itself, the regulations implementing its self-referral prohibition, and guidance provided by the Health Care Financing Administration ("HCFA")—the predecessor to the Centers for Medicare and Medicaid Services ("CMS")—suggest that the answer is "no"; that Stark's self-referral prohibition applies only to Medicare claims. This article discusses Stark's current applicability to Medicaid claims.

The Statute

Both the Stark law itself and the regulations implementing the law suggest that Stark's self-referral prohibition, in its current form, applies only to Medicare claims. First, the Stark law is contained in Subchapter XVIII of Title 42, Chapter 7 of the Social Security Act; the Medicare subchapter.⁵ A separate subchapter—Subchapter XIX—covers Medicaid.⁶ This is important because Stark's self-referral prohibition provides that where a specified financial relationship exists, "the physician may not make a referral . . . for which payment otherwise may be made under this subchapter,"⁷ and "the entity may not present or cause to be presented a claim under this subchapter..."⁸ Because these

provisions are contained in Subchapter XVIII (the Medicare subchapter), the self-referral prohibition would seem to apply only to claims submitted to Medicare.

This placement is also important for purposes of statutory interpretation. As the Supreme Court has held, "'the title of a statute and the heading of a section' are 'tools available for the resolution of a doubt' about the meaning of a statute."⁹ In Florida Department of Revenue v. Piccadilly Cafeterias, Inc., for example, the Supreme Court cited the placement of a statute within a subchapter with a certain heading to help resolve doubt regarding the meaning of the statute.¹⁰ To the extent it is unclear whether Stark's self-referral prohibition applies to Medicaid claims, the fact that the prohibition is contained wholly in the Medicare subchapter, and not the Medicaid subchapter, and expressly limits its application to services "for which payment may be made under this subchapter," strongly indicates that Congress intended Stark's self-referral prohibition to apply only to Medicare. Similarly, the fact that Representative McDermott introduced legislation to amend the Medicaid subchapter to extend Stark's self-referral prohibition to Medicaid is further evidence that, in its current form, the prohibition applies to Medicare only.

Stark Regulations

Applicable federal regulations also suggest that Stark's self-referral prohibition, in its current form, is limited to Medicare claims. Section 411.353 of Title 42 of the Code of Federal Regulations provides, in relevant part, that "a physician who has a direct or indirect financial relationship with an entity, or who has an immediate family member who has a direct or indirect financial relationship with the entity, may not make a referral to that entity for the furnishing of DHS *for which payment otherwise may be made under Medicare.*"¹¹ That same section also provides that "[a]n entity that furnishes DHS pursuant to a referral that is prohibited by paragraph (a) of this section may not present or cause to be presented a claim or bill *to the Medicare program . . .*"¹² and that "*no Medicare payment may be made for a designated health service that is furnished pursuant to a prohibited referral.*"¹³ These regulations are consistent with the statutory language applying the prohibition to Medicare, but not with the notion that the prohibition applies to Medicaid.

Further, the definition of "referral" contained in the Stark regulations also indicates a Medicare-only application. "Referral" is defined to mean either (1) "the request by a physician for, or ordering of, or the certifying or recertifying of the need for, any designated health service *for which*

payment may be made under Medicare Part B...”¹⁴; or (2) “a request by a physician that includes the provision of any designated health service “for which payment may be made under Medicare...”¹⁵ Nothing in the regulations prohibits such referrals in connection with Medicaid patients.

“Stark II” Expansion

Although the language of Stark’s self-referral prohibition does not mention Medicaid, the Stark II legislation, which was passed as part of the Omnibus Budget Reconciliation Act of 1993 (“OBRA 1993”),¹⁶ included a provision that applies an aspect of that self-referral prohibition to Medicaid. Section 1903(s) of the Social Security Act, which is codified at 42 U.S.C. § 1396b(s), provides:

[N]o payment shall be made to a State under this section for expenditures for medical assistance under the State plan consisting of a designated health service . . . furnished to an individual on the basis of a referral that would result in the denial of payment for the service under subchapter XVIII of this chapter if such subchapter provided for coverage of such service to the same extent and under the same terms and conditions as under the State plan....¹⁷

By its plain language, however, Section 1903(s) does not prohibit physicians from referring Medicaid patients to an entity with which the physician has a financial relationship, nor does it prohibit such an entity from submitting claims to Medicaid for services based on such referrals. Instead, Section 1903(s) denies federal financial participation (“FFP”) payment (which is the federal share of Medicaid payments) to a state for designated health services furnished to an individual on the basis of such referrals. This important distinction was made clear in the commentary to HCFA’s proposed rule implementing Stark II:

[Section 1903(s)] denies Federal financial participation (FFP) payment under the Medicaid program to a State for certain expenditures for designated health services. A State cannot receive FFP for designated health services furnished to an individual on the basis of a physician referral *that would result in a denial of payment under the Medicare program* if Medicare covered the services to the same extent and under the same terms and conditions as under the State Medicaid plan.¹⁸

In the commentary to its 1998 proposed rule, HCFA expressly stated that Section 1903(s) was *not* intended to extend Stark’s self-referral prohibition to Medicaid. Under a section entitled “How the referral prohibition and sanctions affect Medicaid providers,” HCFA cited Stark’s self-referral prohibition and stated: “However, we do not believe these

rules and sanctions apply to physicians and providers when the referral involves Medicaid services.”¹⁹ HCFA went on to state that Section 1903(s) “is strictly an FFP provision. It imposes a requirement on the Secretary to review a Medicaid claim, *as if* it were under Medicare, and deny FFP *if* a referral would result in the denial of payment under Medicare.”²⁰ (Importantly, the emphasis here is in the original text). The commentary to HCFA’s proposed rule continued:

Section 1903(s) does not, for the most part, make the provisions in section 1877 [Stark] that govern the actions of Medicare physicians and providers of designated health services apply directly to Medicaid physicians and providers. As such, ***these individuals and entities are not precluded from referring Medicaid patients or from billing for designated health services.*** A State may pay for these services, but cannot receive FFP for them.²¹

Although HCFA was clear in its 1998 proposed rule that, in its opinion, Section 1903(s) did not extend Stark’s self-referral prohibition to Medicaid, it failed to address the issue head-on in subsequent phases of the rulemaking process. In its January 4, 2001, final rule with comment period (Phase I), for example, HCFA stated:

Until OBRA 1993, there were no statutory or regulatory requirements affecting a physician’s referrals for services covered under the Medicaid Programs . . . [Section 1903(s)] extends aspects of the Medicare prohibition on physician referrals to Medicaid. This provision bars FFP in State expenditures for DHS furnished to an individual based on a physician referral that would result in a denial of payment for the services under the Medicare program if Medicare covered the services to the same extent and under the same terms and conditions as under the State Medicaid plan.²²

During Phase I, HCFA stated that it intended “to address the effects of the physician self-referral prohibition on the Medicaid program in Phase II of this rulemaking.”²³ However, when it issued its Phase II interim final rule on March 26, 2004, CMS (as it was called by then) punted the issue:

We had intended to address in this Phase II rulemaking section 1903(s) of the Act, which applies section 1977 of the Act to referrals for Medicaid covered services . . . However, in the interest of expediting publication of these rules, we are reserving the Medicaid issue for a future rulemaking...²⁴

CMS went on to state that “while we have delayed

rulemaking with respect to portions of the application of Section 1903(s)(2) of the Act, the fact that most providers and suppliers of Medicaid services also furnish Medicare services means that the Medicaid programs should indirectly benefit from compliance on the Medicare side.”²⁵ Accordingly, CMS has never held that Stark’s self-referral prohibition applies to Medicaid, and has never retracted its 1998 statement that the self-referral prohibition does not apply to Medicaid.

The DOJ’s Position

Despite the lack of statutory or regulatory support, the DOJ has taken the position in court filings that Stark’s self-referral prohibition applies to Medicaid claims. In a Statement of Interest in response to a defendant’s motion to dismiss an FCA *qui tam*, for example, the DOJ stated that although Stark originally applied only to Medicare claims, OBRA 1993 “extend[ed] the provisions of the Stark Statute to Medicaid claims.”²⁶ Interestingly, however, the DOJ did not argue that Section 1903(s) applied Stark’s self-referral prohibition directly to Medicaid. Instead, the government attempted to connect Stark’s self-referral prohibition to Medicaid in a more indirect way, using the FCA, as follows: (1) The FCA prohibits individuals from submitting, *or causing others to submit*, false claims for payment; (2) Under the Medicaid program, Medicaid providers submit claims for payment to the states, which pay the claims and then seek partial reimbursement from the federal government; (3) Pursuant to 1903(s), the federal government will not reimburse a state for claims based on self-referrals; and (4) Accordingly, by submitting such a claim to a state Medicaid program, the provider causes the state to seek reimbursement from the federal government and, therefore, violates the FCA.²⁷

Tellingly, however, the DOJ did not cite the portion of HCFA’s 1998 proposed rule expressly stating that providers and entities “are *not* precluded from referring Medicaid patients or from billing for designated health services.”²⁸ This might be because it is difficult, to say the least, to reconcile this language with the DOJ’s position that doing just that could result in FCA liability. Moreover, the actual statute and regulations merely prevent the states from collecting FFP for Medicaid services provided pursuant to a self-referral, but *do not* prevent the state from making such a reimbursement.

The Courts Weigh In

Although the DOJ has pursued countless FCA cases predicated upon alleged Stark liability for Medicaid claims, only two federal district courts appear to have addressed this issue head-on; not surprising considering that the overwhelming percentage of FCA cases are resolved by settlement. In *United States ex rel. Baklid-Kunz v. Halifax Hospital Medical Center*, the District Court for the Middle District of Florida adopted the DOJ position outlined above.²⁹ Like the DOJ, however, the court in *Halifax* did not hold that Stark’s self-referral prohibition applies directly to Medicaid.

Instead, the court followed the DOJ’s round-about reasoning: “Accordingly, the Plaintiff’s theory in regard to the Medicaid claims is that the Defendants caused the state of Florida to submit false claims to the federal government for services furnished on the basis of improper referrals. This allegation is sufficient to survive a Rule 12(b)(6) challenge.”³⁰ Once again, however, the court in *Halifax* failed to acknowledge the HCFA’s 1998 guidance that providers and entities are *not* precluded from self-referring Medicaid patients or from billing for such services.³¹ Similarly, in *Parikh*, the district court for the Southern District of Texas adopted the same reasoning, also ignoring HCFA’s 1998 guidance.³²

At least two other courts have stated, in dicta, that Stark’s self-referral prohibition applies to Medicaid. In *Fresenius Medical Care Holdings, Inc. v. Tucker*, the Eleventh Circuit Court of Appeals stated that Stark “prohibits physicians from referring their Medicare and Medicaid patients to business entities in which the physicians or their immediate family members have an interest.”³³ However, *Fresenius* is not controlling for several reasons. First, the court in *Fresenius* was not asked to address the issue of whether Stark’s self-referral prohibition applies to Medicaid and, therefore, the language in question is non-controlling dicta. Second, *Fresenius* was not even a Stark case; instead, the case “involve[d] a constitutional challenge to Florida’s ‘Patient Self-Referral Act of 1992,’” a state statute.³⁴ The federal Stark law was simply mentioned by way of background.³⁵ Finally, the court in *Fresenius* did not cite any authority for the proposition that Stark applied to Medicaid; instead, it simply cited the statute itself and the corresponding regulation, both of which, as discussed above, mention only Medicare.³⁶

Similarly, in *United States v. Rogan*, the district court for the Northern District of Illinois tied Stark’s self-referral prohibition to Medicaid.³⁷ As in *Fresenius*, however, because Stark’s applicability to Medicaid was not at issue in the case, the language of *Rogan* is also non-controlling dicta. Further, the decision in *Rogan* is internally inconsistent with regards to this issue. The court in *Rogan* gives a fairly detailed description of Stark’s self-referral prohibition, expressly stating that the prohibition applies to Medicare, but completely leaving out Medicaid.³⁸

Conclusion

Whether or not Stark’s self-referral prohibition applies to Medicaid claims is not simply a matter for academic debate, as healthcare providers can face, and have incurred, tremendous damages and penalties in Stark and FCA cases. The simple fact is that neither the governing statutes nor the agency’s regulations make Stark’s self-referral prohibition applicable to Medicaid. Although a few courts have been willing to accept, without analysis of the statutory and regulatory language, the DOJ’s argument that Stark’s self-referral prohibition should apply equally to Medicaid claims,

those rulings fly in the face of the plain language of the statute and regulations, as well as agency guidance on the topic. It may be understandable that DOJ would prefer to have Stark apply to Medicaid, but the proper legal mechanism to reach that result is by legislation like that proposed by Representative McDermott and not by argument in a given case that completely ignores the controlling statute. Unfortunately, however, because so few civil healthcare fraud cases reach litigation, this might be an issue confined to academic circles for a long time to come.

¹ H.R. 4676, 113th Cong. (2014).

² For the full text of the bill, see <https://beta.congress.gov/113/bills/hr4676/BILLS-113hr4676ih.pdf>.

³ *Id.*

⁴ 160 CONG. REC. H4475 (daily ed. May 19, 2014) (statement of Rep. McDermott).

⁵ 42 U.S.C. § 1395nn.

⁶ CMS itself has recognized this distinction: “After lengthy national debate, Congress passed legislation in 1965 establishing the Medicare and Medicaid programs as Title XVIII and Title XIX, respectively, of the Social Security Act.” CMS, BRIEF SUMMARIES OF MEDICARE & MEDICAID, TITLE XVIII AND XIX OF THE SOCIAL SECURITY ACT AS OF NOVEMBER 1, 2009, at p.3, available at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/downloads/MedicareMedicaidSummaries2009.pdf>.

⁷ 42 U.S.C. § 1395nn(a)(1)(A) (emphasis added).

⁸ *Id.* § 1395nn(a)(1)(B) (emphasis added).

⁹ *Almendarez-Torres v. United States*, 523 U.S. 224, 234 (1998) (quoting *Trainmen v. Baltimore & Ohio R. Co.*, 331 U.S. 519, 528-29 (1947)).

¹⁰ 554 U.S. 33, 47 (2008).

¹¹ 42 C.F.R. § 411.353(a) (emphasis added).

¹² *Id.* § 411.353(b).

¹³ *Id.* § 411.353(c)(1) (emphasis added).

¹⁴ *Id.* § 411.351 (emphasis added).

¹⁵ *Id.* (emphasis added).

¹⁶ Pub. L. 103-66, 107 Stat. 312 (1993).

¹⁷ 42 U.S.C. § 1396b(s). Tellingly, unlike Stark’s self-referral prohibition, Section 1903(s) was codified in Subchapter XIX of the Social Security Act, which, as discussed above, is the Medicaid subchapter.

¹⁸ 63 Fed. Reg. 1659, 1662 (Jan. 9, 1998) (emphasis added).

¹⁹ *Id.* at 1704.

²⁰ *Id.* (emphasis in original).

²¹ *Id.* (emphasis added).

²² 66 Fed. Reg. 856, 857 (Jan. 4, 2001).

²³ *Id.* at 939.

²⁴ 69 Fed. Reg. 16054, 16055 (March 26, 2004).

²⁵ *Id.* at 16124.

²⁶ United States’ Statement of Interest in Response to Defendants’ Motion to Dismiss, 2013 WL 7897618 (July 26, 2013), at p. 5, *United States ex rel. Parikh v. Citizens Medical Center*, 977 F. Supp. 2d 654 (S.D. Tex. 2013).

²⁷ *Id.*

²⁸ 63 Fed. Reg. at 1704 (emphasis added).

²⁹ No. 6:09-cv-1002, 2012 WL 921147 (M.D. Fla. March 19, 2012).

³⁰ *Id.* at *4.

³¹ Interestingly, in April 2014, over a year after Judge Presnell decided *Halifax*, another district judge in the Middle District of Florida (Judge Whittemore) declined to address the issue of whether Stark applies to Medicaid, finding it unnecessary to reach that issue. No. 8:11-cv-1687, at *5 n.5 (M.D. Fla. April 16, 2013).

³² 977 F. Supp. 2d 654, 665-66 (S.D. Tex. 2013).

³³ 704 F.3d 935, 937 (11th Cir. 2013).

³⁴ *Id.*

³⁵ *Id.*

³⁶ *Id.*

³⁷ 459 F. Supp. 2d 692, 722 (N.D. Ill. 2006).

³⁸ *Id.* at 711-12 (“the Stark Statute . . . prohibits, *inter alia*, a hospital from submitting *Medicare claims* for payment based on patient referrals from physicians having a prohibited ‘financial relationship’ . . . with the hospital”; “Stark I applied to *referrals of Medicare patients* for clinical laboratory services”; “In addition to prohibiting the hospital from submitting claims under these circumstances, the Stark Statute also prohibits payment *by the Medicare program* of such claims”) (emphases added).

Medicare Shared Savings Program Accountable Care Organizations: The Door Nudges Open

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Introduction

Historically, the federal reimbursement programs as well as the general health care economy have been based on a “fee for service” model under which providers, in essence, receive more revenue if they perform more procedures and provide more services. Any economy based on the number of services or items provided is not perpetually sustainable, however. Alternative payment methods must, by necessity, be implemented. Both governmental reimbursement programs and private payors will eventually abandon the traditional fee-for-service model and implement payment systems that require greater provider accountability through an increase in shared financial risk. Future payment systems also will require better management of individual patient health and wellness as a means of controlling overall cost.

Long discussed and now expected to be implemented are alternative payment systems, including pay for performance; hospital-physician bundling for specific diagnosis-related group (DRG) codes; episodic bundling for specific DRG codes, including hospitals, physicians, home health agencies and nursing homes; medical home systems; capitation; and shared-savings models.

One model that might address both private economy and federal budget concerns is the Accountable Care Organization (“ACO”) through which funds are managed in a system that involves “shared financial risk.” In essence, an ACO is a provider network that is involved in collective negotiation of fees for provision of health care services and has the following fundamental components:

- **Monitoring Utilization.** Establishing mechanisms to monitor and control utilization of healthcare services that are designed to control costs and assure quality of care.
- **Measuring Quality.** Clinical protocols must be established to reward the provision of best practices, evidence-based medicine.
- **Selecting Efficient Providers.** Selectively choosing network physicians who are likely to further these efficiency objectives.
- **Investment of Capital.** The significant investment of capital, both monetary and human, in the necessary infrastructure and capability to measure and realize the claimed efficiencies.

Beyond these factors, the ACO must develop a compensation model that will align the incentives of productivity, quality, outcomes, and cost reduction.

Although an ACO can function under a traditional fee for service model (i.e., as a preferred provider organization), the fundamental difference between the independent provider associations (sometimes called “IPAs”) of the past and the ACOs of the future lies in the ACO’s focus on providing services in a coordinated care model under which providers receive compensation based on the provider’s ability to deliver high quality services to a patient population in an efficient and cost-effective manner, rather than receiving compensation based on the volume of services provided or procedures performed. Both providers and payors hope that the ACO model will facilitate improved quality of care through mutual accountability to peers, development and sharing of clinical protocols, breaking down of care “silos,” and driving down costs through efficiency and improved outcomes, resulting in increased net revenues. In short, providers and payors hope to use ACOs to drive down costs and improve quality.

ACOs could well be the wave of the future. This business model can, at least in theory, facilitate competition for new payment methodologies, including hospital-physician bundling, episodic bundling, shared savings models, and capitation models.

Medicare Shared Savings Program ACOs

The permanent presence of ACOs was confirmed with the passage of the Patient Protection and Affordable Care Act of 2010 (ACA), which included the “Medicare Shared Savings Program” or “MSSP” for participating ACOs subject to approval by the Department of Health and Human Services (DHHS), Centers for Medicare and Medicaid Services (CMS). Although CMS is now considering new ACO applications and these statistics will change, as of the last batch of approvals, there are 338 ACOs participating in the MSSP in 47 states plus the District of Columbia and Puerto Rico that are responsible for the care of 4.9 million Medicare beneficiaries. This currently represents only about 10% of all Medicare beneficiaries, but it is clearly a start.

CMS promulgated federal regulations governing formation of ACOs for purposes of MSSP participation in October, 2011. These regulations include following the fundamental elements:

- **Shared Governance.** ACO Participants must have “meaningful participation” in the ACO governing body. With limited exceptions, at least 75% control of the ACO’s governing body must be held by ACO Participants, and the ACO governing board must include a Medicare beneficiary member who is served by the ACO.
- **Accountability.** The ACO must accomplish the “triple aim” of (1) better care for individuals, (2) better health for populations, and (3) lower growth in Medicare expenditures.
- **Term.** The ACO must participate in the MSSP for at least three (3) years.
- **Legal Structure.** The ACO must have a formal legal structure that allows the ACO to receive and distribute “shared savings” payments from CMS to the ACO Participants, but the precise form of the legal structure is not specifically dictated, giving ACOs substantial structural flexibility.
- **Covered Lives.** The ACO must have a minimum of 5,000 Medicare beneficiaries assigned to it. For purposes of Medicare beneficiary assignment, an ACO Participant can participate in only one ACO. The ACO must have sufficient primary care physicians or other practitioners to provide care to the Medicare beneficiaries assigned to the ACO.
- **Clinical Processes.** The ACO governing body must ensure that the ACO has processes in place to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care by use of appropriate technological means.

Early Lessons Learned Regarding Organization of ACOs for MSSP Participation

Although we have limited data on the effectiveness of MSSP participating ACOs to date, we nevertheless can draw a number of important lessons from the experience of MSSP participating ACOs to date, including the following:

- **Anyone Can Own or Operate a MSSP ACO.** While there are precise governance requirements, there are no restrictions on who can own, manage, or operate an ACO.
- **Almost Any Organizational Structure Can Work.** ACO organizational structure typically matches the capitalization responsibility. Our firm has worked with ACOs having the following structures: (i) an equity model in which ACO professionals and private financial investors have an equity

ownership interest, which requires preparation of a comprehensive private placement memorandum under applicable securities laws; (ii) not-for-profit corporations that were originally organized to operate physician-only IPAs with bootstrap capitalization through the IPA dues; and (iii) a limited liability company formed as a wholly-owned subsidiary of a hospital system in which the hospital system supplied all capital.

- **The Biggest Hurdle is Accounting for 5,000 Medicare Beneficiaries Through the ACO.** Because virtually all of our MSSP ACO experience is in middle and smaller markets, enrolling sufficient Medicare beneficiaries to participate in the ACO to meet the statutorily-required minimum of 5,000 “covered” Medicare beneficiary lives is a challenge (especially since ACO Participants can participate in only one ACO). In some markets, competing ACOs are forced to scramble to enroll the required number of Medicare beneficiaries.
- **Designing Shared Savings Distribution Formulas Is Difficult.** There are myriad ways to distribute Shared Savings, and designing an equitable formula can be difficult.
- **CMS Wants the Program to Succeed.** If CMS identifies deficiencies in the ACO application, CMS representatives will work with the ACO to cure the problems. This is in stark contrast to the typical provider-CMS relationship, where the parties are often fiercely adverse.
- **There Is Little Expectation That the MSSP Is Sustainable.** ACOs typically do not believe that the Shared Savings Program has viability beyond a three to five year window. After all, once the “savings” are achieved, it becomes difficult to find more. However, the ACOs all believe that MSSP participation through the ACO will better prepare the ACO Participants for whatever comes next.

Some ACOs Are Beginning to Take a Fresh Look at Physician-Hospital Joint Ventures Under the Federal Fraud and Abuse Law Waivers.

In the fee for service economy, the focus of the federal fraud and abuse laws is preventing improper financial incentives to overutilize health care items and services. In a coordinated care economy, the focus is on managing health care within finite resources and effecting cost savings through proper utilization of health care items and services. Providers must operate within both economic models, and the creation of new and innovative joint ventures models which are well-suited for competing in a coordinated care economy may be at odds with the federal fraud and abuse laws. The federal

regulatory authorities recognized this inherent conflict and the importance of providing guidance to the healthcare community regarding the application of the fraud and abuse laws in order to reconcile the two economic models.

Accordingly, in October 2011 CMS and the DHHS Office of the Inspector General (OIG) issued rules for granting waivers from the application of the three principal federal fraud and abuse laws (the federal Anti-Kickback Statute, the Stark Law, and the Civil Monetary Penalties Law) to joint ventures entered into by ACOs that participate in the Medicare Shared Savings Program. The waivers open the door to development of joint ventures and other contractual arrangements that might otherwise violate those laws and are summarized as follows:

- ACO Pre-Participation Waiver. Provides a waiver of the Stark Law, the federal Anti-Kickback Statute and the Civil Monetary Penalties Law if the parties are acting with good faith intent to develop an ACO that will participate in the MSSP in a specific “target year,” the parties are taking diligent steps to develop the ACO, the ACO’s governing body has made a bona fide determination that the arrangement is reasonably related to the purposes of the Shared Savings Program, and all of the above has been properly documented.
- ACO Participation Waiver. Provides a waiver of the Stark Law, federal Anti-Kickback Statute and the Civil Monetary Penalties Law if the ACO has entered into a MSSP Participation Agreement with CMS, the ACO otherwise fulfills the regulatory requirements for structuring an ACO, the ACO’s governing body has made a bona fide determination that the arrangement is reasonably related to the purposes of the Shared Savings Program, and all of the above has been properly documented. In general, the waiver commences on the date of the Participation Agreement with CMS and terminates upon expiration or termination of the Participation Agreement.
- Shared Savings Distribution Waiver. Provides a waiver of the Stark Law, the federal Anti-Kickback Statute, and the Civil Monetary Penalties Law for distributions and uses of shared savings payments earned under the Medicare Shared Savings Program.
- Compliance With the Stark Law Waiver. Provides a waiver of the federal Anti-Kickback Statute and the Civil Monetary Penalties Law for ACO arrangements that implicate the Stark Law but fall within an existing statutory or regulatory exception to the general prohibition on self-referral for certain items or services to entities with which physicians have financial relationships.

- Patient Incentive Waiver. Provides a waiver of the Civil Monetary Penalties Law and the federal Anti-Kickback Statute for medically related incentives offered by ACOs under the Medicare Shared Savings Program to beneficiaries to encourage preventative care and compliance with treatment regimes.

Two of these waivers stand out.

First, there is a waiver under all federal fraud and abuse laws for any joint venture provided that the ACO’s governing body has made a bona fide determination that the arrangement is “reasonably related to the purposes of the Shared Savings Program.” This opens the door, for example, to imaging joint ventures or organization of medical clinics involving hospitals and physicians unfettered by compliance concerns.

Second, any arrangement that otherwise complies with the Stark Law is deemed not to have violated the Anti-Kickback Statute. This closes the gap between what is permissible under the Stark Law exceptions and what is considered “safe” under the Anti-Kickback Statute safe harbor regulations.

Creative ACOs Are Using the Structure Developed for MSSP Participation for Private Market Purposes.

Once an ACO that participates in the MSSP becomes operational, the ACO can be used for other market purposes. Creative ACOs are using this foundation to negotiate shared savings arrangements with private payers, and to prepare for participation in other innovative payment arrangements.

The most important concern in that regard is compliance with antitrust law.

While the ACA empowers one federal agency, CMS, to approve ACOs for purposes of participating in the MSSP, these efforts must meet antitrust law compliance as regulated by the Federal Trade Commission (FTC) and the Antitrust Division of the United States Department of Justice (DOJ). This clash of federal agency powers resulted in joint promulgation by the FTC and DOJ in October 2011 of a new “safety zone” for ACOs participating in the MSSP. In issuing this guidance, the FTC and DOJ acted to provide health care providers with much needed guidance regarding the application of anti-trust laws to ACO arrangements and activities, allowing providers to form pro-competitive ACOs and participate in both the Medicare and commercial markets. The “safety zone” included the following provisions:

- FTC and DOJ Business Review Process. The FTC and DOJ will provide a ninety (90) day expedited antitrust review to all ACOs (which is entirely voluntary and not required).

- **ACO Antitrust Safety Zone.** In general, an ACO antitrust “safety zone” applies to ACO participants who provide the same “common service” and have a combined share of thirty percent (30%) or less of each common service in the primary service area. Higher market shares of physician services may still be “safe” if the primary service market is in a rural area.
- **“Rule of Reason” Application.** ACOs that do not fall within the ACO safety zone will be evaluated by the FTC and DOJ under the “rule of reason,” which balances potential anti-competitive effects of the ACO against its potential pro-competitive effects. Specifically, the FTC and DOJ will apply the “rule of reason” “if providers are financially or clinically integrated and the agreement is reasonably necessary to accomplish the pro-competitive benefits of the integration.”
- **Potentially Problematic Conduct.** The FTC and DOJ identified the following as examples of potentially problematic conduct:
 - the rise of certain “anti-steering,” “anti-tiering,” “guaranteed inclusion,” “most favored nation,” or similar contract provisions;
 - tying sales of the ACOs services to a private payor’s purchase of other services from providers outside of the ACO, especially providers affiliated with an ACO participant;
 - exclusive contracting with ACO physicians, hospitals, ASCs, or other providers that may discourage or prevent those providers from contracting with private payors outside the ACO; and
 - restricting a private payor’s ability to make certain information about the ACO’s cost, quality, and efficiency available to the payor’s covered beneficiaries.

Conclusion

While MSSP ACOs are only beginning to emerge, and many providers have decided that MSSP participation is not worth the potential return, the providers who are embracing the Shared Savings Program and forming ACOs are using the program to create new ventures and explore new coordinated care payment models, all of which bode well for survival in a changing health care economy.

“Meaningful Use”: Payments and Penalties Under the Medicare and Medicaid Electronic Health Record Incentive Programs

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Introduction: The Medicare and Medicaid EHR Incentive Programs

Created under the Health Information Technology for Economic and Clinical Health Act of 2009 (“HITECH Act”), the Medicare and Medicaid EHR Incentive Programs encourage health care providers to adopt electronic health record (“EHR”) technology in ways that can positively impact patient care. Specifically, the EHR Incentive Programs provide payments to eligible professionals and hospitals as they adopt, implement or upgrade certified EHR technology. The Centers for Medicare and Medicaid Services (“CMS”), which manages the programs, estimates that from their inception in 2011 through August 2014, the programs have paid over \$16 billion in incentives to over 490,000 eligible providers and hospitals that have demonstrated “meaningful use” of certified EHR technology.¹ 2014 marks the final year in which providers may begin participation in the programs, and the incentives will be gradually phased out over the next two years. Beginning in 2015, providers who do not successfully demonstrate meaningful use of EHR will be subject to a 1% “adjustment” (*i.e.*, reduction) of their Medicare reimbursements, which will increase to a maximum of 5% over time for providers that continue to fail to demonstrate meaningful use.²

Eligibility

The eligibility criteria for participation in the EHR Incentive Programs differ depending on whether the provider is a “professional,” *i.e.*, an individual practitioner, or a hospital. Eligible professionals under the Medicare EHR Incentive Program include:

- Doctors of medicine or osteopathy;
- Doctors of dental surgery or dental medicine;
- Doctors of podiatry;
- Doctors of optometry; and
- Chiropractors.³

Hospital-based professionals, defined as professionals who perform 90% or more of their services in a hospital inpatient or emergency room setting, are not eligible for incentive payments. Professionals who are part of a practice may qualify for separate incentive payments if each eligible professional successfully demonstrates meaningful use of certified EHR technology. Each eligible professional is only eligible for one incentive payment per year, regardless of how

many practices or locations at which he or she provides services.

Eligible hospitals under the Medicare EHR Incentive Program include:

- General, acute care, short-term hospitals in the 50 states or D.C. that are paid under the Inpatient Prospective Payment System;
- Critical Access Hospitals; and
- Medicare Advantage Affiliated Hospitals.

The pool of eligible professionals for the Medicaid EHR Incentive Program is somewhat broader than under the Medicare program, and includes nurse practitioners, certified nurse-midwives, and certain types of physician assistants in addition to physicians and dentists.⁴ The Medicaid EHR Incentive Program has the added requirement that the professional must either (i) have a minimum 30% Medicaid patient volume (or 20% if the professional is a pediatrician), or (ii) practice predominantly in a Federally Qualified Health Center or Rural Health Center and have a minimum 30% patient volume attributable to needy individuals. Professionals who are eligible for both the Medicare and Medicaid EHR Incentive Programs may not participate in both, but must choose which program they wish to participate in when they register.

Eligible hospitals under the Medicaid EHR Program are either (i) acute care hospitals (including CAHs and cancer hospitals) with at least 10% Medicaid patient volume, or (ii) children's hospitals (no Medicaid patient volume requirements). Unlike professionals, hospitals may be dually-eligible for both Medicare and Medicaid EHR incentive payments.

Certified EHR Technology

EHR generally refers to technology that allows providers to record patient information in electronic form, as opposed to traditional paper records. However, providers wishing to participate in the EHR Incentive Programs must use EHR technology that is certified specially by CMS and the Office of the National Coordinator for Health Information Technology (“ONC”). EHR technology must satisfy certain standards and criteria for structured data established by CMS and ONC in order to be considered certified EHR technology (“CEHRT”) and thus qualify the provider using it for incentives. Specifically, CEHRT must:

- (1) incorporate patient demographic and clinical health information, such as medical history and problem lists; and
- (2) have the capacity:
 - (i) to provide clinical decision support;
 - (ii) to support physician order entry;
 - (iii) to capture and query information relevant to health care quality; and
 - (iv) to exchange electronic health information with, and integrate such information from other sources.⁵

A complete list of CEHRT products is available at <http://www.healthit.gov/policy-researchers-implementers/certified-health-it-product-list-chpl>.

There are currently two editions of certification criteria for CEHRT, one adopted in 2011 and another in 2014. Originally, CMS intended for all eligible providers to adopt, implement or upgrade to 2014 edition CEHRT in order to demonstrate meaningful use starting in 2014. However, many providers and EHR technology vendors expressed concern that backlogs in the certification process were delaying or limiting the availability of many 2014 edition CEHRT products. In response, and in an effort to grant more flexibility to providers who were having difficulty implementing 2014 edition CEHRT, CMS advised that it would allow such providers to continue to use 2011 CEHRT or a combination of 2011 and 2014 edition CEHRT for the EHR reporting periods in 2014.⁶

Meaningful Use

In order to receive EHR incentive payments, providers must do more than simply own or use CEHRT. Providers must show that they are using EHR in “meaningful” ways – i.e., in ways that can positively affect the care of their patients. To do this, providers must meet certain objectives established by CMS. These objectives are organized in three stages, each with its own set of requirements. Regardless of when they enter the program, providers begin in Stage 1 and then progress through Stages 2 and 3. Providers progress through the stages in accordance with a timeline created by CMS, and each year eligible providers must “attest” to CMS that they have satisfied the objectives for the particular stage that they are in.

The attestation process relies on self-reporting by providers, similar to the process of filing tax returns. A provider seeking incentive payments simply visits a CMS website, registers, and enters data demonstrating that it has satisfied the objectives of the applicable Stage. There is little prepayment review by CMS. However, CMS does conduct post-payment audits, and audited providers who are unable to verify satisfaction of the meaningful use objectives with

supporting documentation are subject to the loss of any incentive payments received as well as other penalties.

Participating providers who fail to demonstrate meaningful use or fail an audit in a given year may, and in fact are “highly encouraged,” to continue participating in the programs in future years.⁷ CMS has advised that each participation year is considered independent, and a failed audit or failure to attest to meaningful use in one year will not affect future years.⁸ Providers in these circumstances must continue along the timeline established by CMS and meet the meaningful use standards for the following year. For example, most providers must meet two years of meaningful use under the Stage 1 criteria before advancing to Stage 2 criteria in their third year of participating. If such a provider successfully demonstrates the Stage 1 criteria for the first payment year, but does not meet the Stage 1 criteria in the second payment year, the provider will receive an incentive payment for the first year but not the second. When that provider proceeds to attest for the third payment year, it will be expected to demonstrate the Stage 2 meaningful use criteria, because it has already completed the first and second program years, even if it did not meet the Stage 1 criteria in the second year.

Stage 1

The requirements for Stage 1 are focused on providers capturing patient data and sharing that data either with the patient or with other healthcare professionals.⁹ The specific objectives a provider must meet to demonstrate meaningful use under Stage 1 depend on which edition of CEHRT the provider is using. Providers who have fully implemented 2014 edition CEHRT are subject to slightly different requirements, referred to as the “2014 Definition” of Stage 1 meaningful use, while providers who are using either 2011 edition CEHRT or a combination of 2011 and 2014 edition CEHRT may elect instead to follow the objectives and measures outlined in the “2013 Definition.”¹⁰ The applicable requirements also differ slightly depending on whether the provider is a professional or a hospital.

2013 Definition

Under the 2013 Definition of Stage 1 meaningful use, eligible professionals must meet a total of 18 objectives, 13 of which are required “core objectives,” with the other 5 chosen from a list of 10 “menu objectives.” The core objectives are as follows:

- (1) Using computer provider order entry (“CPOE”) to enter at least one prescription order for at least 30% of patients who have a medication listed in the EHR;
- (2) Implementing drug-drug and drug-allergy interaction checks;

- (3) Maintaining an up-to-date list of current diagnoses for more than 80% of the provider's patients;
 - (4) Transmitting more than 40% of all prescriptions written by the provider electronically (as opposed to transmitting by phone or fax);
 - (5) Maintaining an active medication list for more than 80% of all the provider's patients;
 - (6) Maintaining an active medication allergy list for more than 80% of the provider's patients;
 - (7) Recording demographic information, including gender, race, ethnicity, date of birth, and preferred language, for more than 50% of the patients seen by the provider;
 - (8) Recording and charting vital signs, including height, weight, and blood pressure, for more than 50% of all patients over age 2 seen by the provider;
 - (9) Recording smoking status for more than 50% of all patients 13 years or older;
 - (10) Implementing one clinical decision support rule (a function which allows providers to program the CEHRT to trigger an alert or other clinical information when they encounter patients with certain diagnoses or treatments);
 - (11) Providing electronic copies of health records to more than 50% of patients who request it within 3 business days of the request;
 - (12) Providing clinical summaries to patients for more than 50% of all office visits within 3 business days; and
 - (13) Protecting EHR by conducting a security review of the provider's EHR system and correcting any deficiencies that could make patient information vulnerable.¹¹
- (4) Recording in the EHR the results of over 40% of lab tests ordered by the professional during the reporting period;
 - (5) Generating at least one report listing patients of the professional with a specific condition relevant to the professional's practice;
 - (6) Sending preventative or follow-up care reminders to over 20% of patients aged 65 years or older or 5 years or younger;
 - (7) Providing electronic access to EHR, such as through an online portal, for at least 10% of patients within 4 business days of any update to their health information;
 - (8) Using CEHRT to provide patient-specific education resources to over 10% of patients;
 - (9) Performing medication reconciliation for more than 50% of patients transitioned into the professional's care from another provider; and
 - (10) Sending a summary of care generated by the professional's CEHRT for over 50% of the patients the professional refers to another provider or transfers to another care setting.¹²

The 10 "menu objectives" from which eligible professionals may choose are:

- (1) Testing their CEHRT's ability to submit electronic data to immunization registries;
- (2) Testing their CEHRT's ability to submit syndromic surveillance data to public health registries;
- (3) Enabling CEHRT functionality to check potential medication orders against a drug formulary;

Eligible hospitals must meet twelve required core objectives and 5 menu objectives, for a total of 17. For hospitals, the core objectives are the same as for professionals, with the exceptions that (i) hospitals are not required to meet objective number 4 regarding the electronic transmission of prescriptions, (ii) along with the other demographic information, hospitals must also report the date and preliminary cause of death in the event of patient mortality, and (iii) instead of providing clinical summaries, hospitals must provide patients with electronic copies of their discharge instructions at the time of discharge, upon request.¹³ In addition, 8 of the ten menu objectives are the same for hospitals as they are for professionals. The exceptions are that hospitals are not required to meet the professional menu objectives for sending patient reminders or providing patients with access to their health information. These objectives are replaced in the hospital menu objectives with options to (i) record advanced directives for patients aged 65 years or older or (ii) test their CEHRT's ability to submit electronic data on reportable lab results to public health agencies.¹⁴

2014 Definition

The requirements for eligible professionals under the 2014 Definition of Stage 1 meaningful use are largely the same as the requirements under the 2013 Definition, with a few exceptions. First, the core requirement to provide electronic copies of health records to patients is replaced with a requirement to provide patients with the ability to view

online, download, and transmit their health information within four business days of the information being available to the professional.¹⁵ Second, the core requirement to record and

chart vital signs is changed to increase the age limit for recording blood pressure in patients to age three, and to remove the age limit for recording height and weight.¹⁶ Third, the option to provide electronic access to health records has been removed from the list of 10 menu objectives.¹⁷

There are even fewer changes to the requirements for hospitals under the 2014 Definition. The same changes to the core objectives from the 2013 to the 2014 Definitions for professionals also apply to hospitals.¹⁸ However, the menu objectives for hospitals remain the same under the 2013 and 2014 Definitions.¹⁹

Stage 2

According to CMS, Stage 2 includes new objectives to improve patient care through better clinical decision support, care coordination, and patient engagement.²⁰ The point at which a provider will transition from Stage 1 to Stage 2 depends on when it began participation in the EHR Incentive Programs. Providers who began participating in 2011 must meet three consecutive years of meaningful use under the Stage 1 criteria before advancing to the Stage 2 criteria in 2014. All other providers must meet two years of meaningful use under the Stage 1 criteria before advancing to the Stage 2 criteria in their third year.²¹ Stage 2 retains the core and menu structure for meaningful use objectives. Although some Stage 1 objectives were either combined or eliminated, most of the Stage 1 objectives are core objectives under the Stage 2 criteria. For many of these Stage 2 objectives, the threshold that providers must meet for the objective has been raised.

To demonstrate meaningful use under Stage 2 criteria, eligible professionals must satisfy 20 total objectives: 17 core objectives plus 3 menu objectives selected from a list of 6. The core objectives for professionals in Stage 2 are as follows:

- (1) Using CPOE to enter at least 60% of medication orders, 30% of laboratory orders, and 30% of radiology orders created by the professional during the reporting period;
- (2) More than 50% of all prescriptions written by the professional must be compared to at least one drug formulary and sent electronically using CEHRT;
- (3) Recording demographic information, including gender, race, ethnicity, date of birth, and preferred language, for more than 80% of the patients seen by the provider;
- (4) Recording and charting vital signs, including blood pressure for more than 80% of patients aged 3 or

older, and height and weight for more than 80% of patients of any age;

- (5) Recording smoking status for more than 80% of all patients 13 years or older;
- (6) Implementing five clinical decision support rules;
- (7) Providing online access to health information to more than 50% of patients within 4 business days and ensuring that more than 5% of patients actually view, download or transmit to a third party their available health information;
- (8) Providing clinical summaries to patients for more than 50% of all office visits within 1 business day;
- (9) Protecting EHR by conducting a security review of the provider's EHR system and correcting any deficiencies that could make patient information vulnerable;
- (10) Recording results from over 55% of lab tests ordered by the professional during the reporting period which yield either a positive/negative or numerical result;
- (11) Generating at least one report listing patients of the professional with a specific condition relevant to the professional's practice;
- (12) Sending preventative or follow-up care reminders to more than 10% of patients who have had two or more office visits with the professional within the last 24 months;
- (13) Using CEHRT to provide patient-specific education resources to over 10% of patients;
- (14) Performing medication reconciliation for more than 50% of patients transitioned into the professional's care from another provider;
- (15) Sending a summary of care generated by the professional's CEHRT for over 50% of the patients the professional refers to another provider or transfers to another care setting (of the summaries generated, 10% must be sent electronically and at least one must be sent to a recipient using a different EHR vendor or to a designated CMS "test" EHR);
- (16) Ensuring that their CEHRT is successfully submitting electronic data to immunization registries on an ongoing basis; and
- (17) Ensuring that at least 5% of patients send secure messages to the professional using the electronic

messaging function of the professional's CEHRT.²²

The six menu objectives from which eligible professionals may choose to demonstrate meaningful use under Stage 2 are:

- (1) Ensuring that their CEHRT is successfully submitting syndromic surveillance data to public health registries on a continuing basis;
- (2) Entering at least one electronic progress note into the EHR for more than 30% of patients with at least one office visit during the applicable reporting period;
- (3) Ensuring that more than 10% of imaging test results ordered during the reporting period are available through the CEHRT;
- (4) Recording family health history in the EHR;
- (5) Ensuring that their CEHRT is successfully submitting cancer case information to a public health cancer registry on a continuing basis; and
- (6) Successfully submitting specific case information from their CEHRT to a specialized registry.²³

Under Stage 2, eligible hospitals and CAHs must satisfy a total of 19 objectives: 16 core objectives plus 3 menu objectives selected from a list of 6. For hospitals, the core objectives are the same as for eligible professionals, with the exceptions that (i) hospitals are not required to meet objectives 2, 8, 12, and 16 regarding electronic transmission of prescriptions, providing clinical summaries, patient reminders, and electronic messaging with patients, respectively, (ii) hospitals must ensure that their CEHRT is successfully transmitting reportable laboratory results and electronic syndromic surveillance data to public health agencies on a continuing basis, and (iii) hospitals must automatically track medications from order to administration using an electronic medication administration record.²⁴ The six menu objectives from which eligible hospitals may choose are:

- (1) Recording whether patients aged 65 years or older have advanced directives;
- (2) Entering at least one electronic progress note created, edited and signed by an authorized provider of the hospital's inpatient or emergency department for more than thirty percent (30%) of the hospital's I/P or ED admissions;
- (3) Ensuring that more than 10% of imaging test results consisting of the image itself and any explanation or other accompanying information are accessible through the CEHRT;

- (4) Recording patient family health history in the EHR;
- (5) Generating and transmitting discharge prescriptions electronically (eRx); and
- (6) Providing electronic laboratory results to ambulatory providers.²⁵

Stage 3

CMS has not yet finalized the requirements for Stage 3 Meaningful Use. Final rules for these requirements are expected in the first half of 2015.

Goodbye Carrot, Hello Stick

Beginning on January 1, 2015, eligible professionals and hospitals that have not demonstrated meaningful use of EHR technology will be subject to reductions in the payments they receive from Medicare.²⁶ For professionals, this payment adjustment will be applied to the Medicare physician fee schedule amount for covered professional services furnished during the year. These reductions will increase over time, starting with a 1% reduction in reimbursements for providers who do not meet EHR standards in 2015, 2% in 2016, and 3% from 2017 going forward. These deductions may increase further if the proportion of providers nationwide does not reach certain benchmarks. Specifically, beginning in 2018, if less than 75% of all eligible providers have demonstrated meaningful use of EHR, then the payment reduction will increase by one additional percentage point from the previous year, with a maximum total reduction of up to 5%.

Conclusion

The EHR Incentive Programs and the meaningful use standards underlying them reflect the government's stated goals of improving care coordination, quality, safety, and efficiency in the delivery of health care services.²⁷ The government's hope is that widespread compliance with the meaningful use objectives will result in better health outcomes for patients as well as increased transparency and efficiency in the health care system as a whole. Certain aspects of the programs have been criticized by providers, vendors, and commentators, with many calling for changes to give providers more time to integrate complicated and burdensome, if ultimately beneficial, EHR technology into their practices.²⁸ While CMS has indicated some willingness to make minor changes to the programs, such as extending compliance deadlines and providing hardship exemptions, meaningful use requirements are here to stay. Barring some unforeseen changes, all providers will eventually have to implement and demonstrate meaningful use of EHR technology if they wish to avoid penalties that could significantly impact their bottom lines.

¹ http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/August2014_SummaryReport.pdf.

² 42 C.F.R. § 495.102(d).

³ 42 C.F.R. § 495.100; *see also* <http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/eligibility.html>.

⁴ 42 C.F.R. § 495.304.

⁵ 42 C.F.R. § 495.4 and 45 C.F.R. § 170.102.

⁶ The Final Rule was published in the September 4, 2014 Federal Register, 79 F.R. 52910.

⁷ See <https://questions.cms.gov/faq-php?faqID=9220>.

⁸ See id; <http://ehrintelligence.com/2013/09/18/how-does-a-failed-meaningful-use-audit-affect-providers/>.

⁹ http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/downloads/Beginners_Guide.pdf, p. 8.

¹⁰ http://cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/2013Definition_Stage1_MeaningfulUse.html.

¹¹ 42 C.F.R. § 495.6(d).

¹² 42 C.F.R. § 495.6(e).

¹³ 42 C.F.R. § 495.6(f).

¹⁴ 42 C.F.R. § 495.6(g).

¹⁵ 42 C.F.R. § 495.6(d)(12).

¹⁶ 42 C.F.R. § 495.6(d)(8).

¹⁷ 42 C.F.R. § 495.6(e)(5).

¹⁸ 42 C.F.R. § 495.6(f).

¹⁹ 42 C.F.R. § 495.6(g).

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http://www.cms.gov/eHealth/downloads/eHealthU_EPsGuideStage2EHR.pdf.

²¹ http://cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Stage_2.html.

²² 42 C.F.R. § 495.6(j).

²³ 42 C.F.R. § 495.6(k).

²⁴ 42 C.F.R. § 495.6(l).

²⁵ 42 C.F.R. § 495.6(m).

²⁶ 42 C.F.R. § 495.102(d).

²⁷ <http://www.healthit.gov/providers-professionals/meaningful-use-definition-objectives>.

²⁸ *See, e.g.,* Kaufman, Lena, *Criticism of EHR Incentive Program Grows*, available online at <http://www.healthxo.com/topics/health-it/criticism-ehr-incentive-program-grows>.