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Lions and Tigers and Bears, Oh My! The Unexpected Laws that May Affect Your Telehealth Business

Carol Lucas, Esq.

An increasing number of health care providers are exploring telemedicine, either as an adjunct to their primary physical practice or as a separate and new venture. Providers have determined that many aspects of the service they provide can be effectively provided remotely if the technology and the tools are adequate. However, when a provider expands from single-state practice to potentially fifty state practice, the legal and regulatory regime that the provider is used to may not translate to all of the provider's new practice locations. In fact, it almost certainly will not and telehealth providers need to review a number of different regulatory regimes in each state they propose to practice in.

For the most part, these telehealth providers understand generally that they need to comply with the laws of the states in which the recipients of their services are located. A physician physically located in Missouri, for example, could treat a patient located in California if the physician is licensed in California, the state in which the patient resides. That physician most likely also understands that California law may have something to say about whether telemedicine is appropriate, and, if so, what requirements apply to it. For example, provision of services by means of telehealth technology does not eliminate California's requirement to obtain a patient's informed consent. However, that consent may be either oral or in writing and the healthcare provider who obtains the consent need not be at the site where the patient is. Further, for California, the physician must conduct an "appropriate" initial examination. Depending on the nature of the service, that examination could be accomplished remotely, but may need to be conducted in-person. The California Medical Board leaves that decision to the professional judgment of the physician.

Not so Texas. The Texas Medical Board recently adopted new rules that require an in-person examination in order to establish a physician-patient relationship, a prerequisite to the delivery of services via telemedicine if the services include prescribing medication. Further, the in-person examination must take place in an "established medical site."

Other laws that vary state to state also affect the delivery of telemedicine services. These include: the corporate practice of medicine; laws relating to prescribing (such as Texas's new rules) or physician dispensing; and laws requiring language services.

Corporate Practice of Medicine:
The corporate practice of medicine prohibition generally prohibits lay (i.e., non-professional) entities from providing medical services. In most corporate practice states (including California), that means that a general business corporation cannot charge for physician services. A telemedicine provider located in a state without a corporate practice ban may be organized as a general business entity and may employ physicians. If that telemedicine provider were to provide services to a patient in California through a California licensed physician employee, the payment by the California patient to the telemedicine provider could be held to violate California's corporate practice ban. Further, California does not permit foreign (i.e., sister-state) professional corporations to practice in California. New York, on the other hand, permits the qualification of foreign professional service corporations in New York, provided that all of the

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shareholders, officers, and directors are licensed to practice medicine in New York.

Physician Dispensing: If the telehealth provider dispenses medication to patients in remote locations, laws relating to physician dispensing will be implicated. The New York Board of Pharmacy takes the position that physicians may not dispense in New York at all. In California, physicians may dispense as long as they comply with all statutory requirements regarding labeling, etc. Florida permits physician dispensing upon registration with the Florida medical licensing board as a dispensing practitioner and compliance with pharmacy disclosure regulations.

Language Interpretation Services: States also vary widely in requirements to provide language interpretation services. For example, Mississippi specifically requires telemedicine equipment and the network for remote patient monitoring services to accommodate non-English language options. New Hampshire requires hospitals to provide interpretation services during admission and imposes interpretation requirements on long-term care facilities and mental health facilities. New Hampshire does not, however, require physicians to provide interpretation services to non-English speaking patients, either in person or remotely.

For telemedicine providers, licensing laws are only the starting point. Telemedicine providers should be aware that a business model that complies with one state's laws may not be exportable without review and some tweaking.

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Removing the Barriers to Coordinated Care: the Stark Law

Mitchell J. Olejko, Esq.

August 10, 2015 was the 22nd anniversary of the expansion of the Medicare self-referral prohibition to include 10 "designated health services" in addition to clinical laboratory tests.[1] This law is the so-called Stark Law. January 1, 2015 was the 20th anniversary of the effective date of these changes. The purpose of the Stark Law was to establish a "bright-line" test separating prohibited self-referrals from referrals that are part of the normal workings of the health care system.[2]

Since enactment, there have been 29 significant regulatory actions taken by the Centers for Medicare & Medicaid Services ("CMS") to interpret and apply the Stark Law. According to former Congressman Fortney "Pete" Stark: "Pretty soon the law got to be as thick as a phonebook for all the exemptions for this, that and the other thing."[3]

On July 15, 2015, the 30th significant regulatory action was taken by CMS when it proposed further rules under the Stark Law.[4] In general, this proposed rule would have many benefits – among other things clarifying points of interpretation within the regulations (the "Stark Rule").[5]

One of the most important aspects of the Proposed Rule is the existing Stark Law and Stark Rule are perceived as barriers to attempts by hospitals, physicians and others to achieve health system reform as envisioned by recent federal actions. CMS stated in the preamble to the Proposed Rule that: "[s]ince the enactment of Section 1877 of the [Social Security] Act in 1989, significant changes in the delivery of health care services and the payment for such services have occurred, both within the Medicare and Medicaid programs and with respect to non-federal payors."[6] Proposed Rule 41927. This is something of an understatement. CMS then stated that it has "engaged in efforts to align payment under the Medicare program with the quality of care provided to our beneficiaries." *Id.* CMS then enumerated the many actions taken by Congress over the last decade and implemented by CMS to achieve this purpose. Proposed Rule 41927-41928. The electronic health records initiative, while not mentioned by CMS, will contribute importantly to achieving these goals. CMS correctly found that stakeholders are concerned whether innovative payment approaches outside of the Medicare Shared Savings Program or CMS-sponsored initiatives and other federal health care initiatives would run afoul of Stark. Proposed Rule 41928-41929. Such concerns extend to arrangements involving non-federal payors because of the broad reach of the Stark Law's definition of a financial arrangement.

Congress and CMS are to be commended for continuing efforts aimed at payment system reform and CMS is to be commended for calling for comments to address this issue (Proposed Rule

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Avoiding the Costly "Robo No-No"

Julie Simer, Esq.

The Telephone Consumer Protection Act ("TCPA") was enacted to protect consumers from intrusive robocalls, but Congress probably did not foresee that it would result in a windfall for plaintiff's lawyers. Virtually every industry that provides goods or services to consumers has faced TCPA class actions, from sports franchises[1] to oil change service companies.[2] Thus, it should come as no surprise that the health care industry has had its share of TCPA class actions. For example, Walgreens recently agreed to an $11 million settlement of TCPA class action litigation relating to its prescription reminders.[3]

In general, the TCPA makes it unlawful for a person to call the cellular telephone number of any other person using an automated telephone dialing system without the recipient's prior express consent.[4] The term "call" includes both voice and text messages.[5] The TCPA provides for a private right of action and statutory damages of $500 per violation, and up to $1,500 per violation for willful or knowing violations.[6] Plaintiffs can recover even if they have suffered no actual damages.
One key issue in the TCPA litigation is whether the consumer has given express consent to automated calls and texts. The vast majority of cases to address the issue have held that a telephone customer who provides her number to another party consents to receive calls or texts from that party.[7] On July 10, 2015, the FCC released a Declaratory Ruling and Order ("FCC July 2015 Order") which suggests there is not a specific method by which a caller must obtain prior express consent, only that the consent must be express and not implied or presumed. Although defendants cannot be held directly liable for violations of the TCPA if they have had no involvement in placing the calls, in some instances they may be held vicariously liable for a third-party's actions.[8]

A second key issue is whether express consent was given to the defendant or to some other party. In *Hines v. CMRE Financial Services, Inc.*, Hines sought treatment at the Town & Country Hospital in Tampa, Florida ("Hospital").[9] Prior to admission, Hines provided his cellular telephone number to the Hospital. The Town & Country Emergency Physicians, LLC ("TCEP"), who were under contract with the Hospital, provided emergency services to Hines. TCEP billed Hines for the services provided, but when Hines did not pay his bill TCEP obtained Hines's telephone number from the Hospital and retained a third-party, CMRE, to collect the debt. In the course of its debt-collection efforts, CMRE placed 153 automated calls to Hines's cellular telephone. The U.S. District Court for the Southern District of Florida held that although Hines provided his telephone number to the Hospital upon admission, he did not give "prior express

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Delivering Health Care Services to Consumers through eHealth Devices: The Role of State Professional Practice Laws

Kathleen Juniper, Esq.

Smart medical devices that can deliver health care services are increasingly consumer friendly. Using the latest technologies and sophisticated algorithms, some devices are capable of collecting data directly from consumers then providing them with diagnoses and prescriptions for treatment, equipment and products. Companies producing these devices are eager to market and deliver their products and services directly to defined demographic consumer groups for certain low-risk health conditions. The marketing campaigns and business models they use for national expansion, including how licensed practitioners are involved, depend upon the application of state professional practice laws.

Professional practice laws govern who can collect patient data, administer tests, make diagnoses, determine treatment plans and issue prescriptions, among other things. These laws vary by state and are based on product-by-product and professional license-by-license categories. The laws may dictate the relationship between the device and licensed practitioners and ultimately determine a company's organizational structure. Further, professional practice laws may define the content of advertising for the medical devices and the health conditions they address. Typically, violations of these professional practice laws are classified as misdemeanors.

Many of these laws were enacted decades ago when legislators never contemplated telehealth and the advanced technology of today's medical devices. Often, state professional licensing boards will apply the laws to these innovative devices – even if the laws may not specifically address them; for example, they may allege that the device company is illegally engaged in the practice of medicine. Where a board determines that the device services can be delivered only by licensed practitioners or takes actions that effectively exclude the device company from the market, the board's motivations need to be scrutinized. Although a professional licensing board (comprised of the practitioners the board regulates) can protect the public's health and safety, a board cannot engage in anticompetitive conduct aimed at protecting their own financial interests as licensed practitioners. *See North Carolina Board of Dental Examiners v. Federal Trade Commission*, 135 S. Ct. 1101 (2015).

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41929-41930). However, we do not believe regulatory action will be either sufficient or timely enough to address this issue. Payment system changes that align "payment ... with quality of care ..." would solve the issue the Stark Law was intended to address – that is, overutilization driven by the prospect of financial gain.[7] Our concern is that CMS does not have sufficient regulatory authority to accomplish these laudatory goals and that the Stark Law, like a 20-year old car, perhaps can be fixed but the better approach is a fresh solution. If repeal is not in the offing, then Congress should enact a broad exception for arrangements that connect payment to health care quality and that seek to reward achieving the so-called "Triple Aim," while at the same time providing for the sunset of the Stark Law.[8] Repeal or sunset of the Stark Law would leave in place many protections against crimes such as theft committed against federal and state programs. These protections include the federal Anti-Kickback Statute and the False Claims Act, although these statutes too will become outdated to be replaced with statutes that focus on quality of care and utility of services.

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1 PL 103-66, § 13562 (Aug. 10, 1993); Section 1877 of the Social Security Act.
2 *See, e.g.*, 66 Fed. Reg. 856, 860 (Jan. 4, 2008).
3 Janet Adamy, Wall Street Journal, *Pete Stark: Law Regulating Doctors Mostly Helped Lawyers*, http://blogs.wsj.com/washwire/2014/10/22/pete-stark-law-regulating-doctors-mostly-helped-lawyers/ (Oct. 22, 2014) accessed Aug. 17, 2015.
4 80 Fed. Reg. 41685 (pp. 41909-41930, 41933-41958) (July 15, 2015) ("Proposed Rule").
5 For example, all who have spent time trying to understand the difference that results from the use of the term arrangement in one instance and agreement in another when applying the Stark Rule may soon be relieved of that task. Proposed Rule 41916.
6 1989 was the enactment date of the Stark Law as it related to clinical laboratory services.
7 Of course, the reciprocal concern is the fear that certain payments might encourage reduction of services to Medicare beneficiaries. Notably, as part of Congress's fix of the "sustainable growth rate," Section 1128A((b)(1) limited the applicable civil money penalty to payments to reduce or limit "*medically necessary*" services. PL 114-10, Section 512 (April 15, 2015).
8 The "Triple Aim" or "three-part aim" today includes improving the health of populations, improving the experience of care and reducing per-capita costs of health care.

New Texas Legislation Helps "Stretch" The Concepts of Narrow Networks

Scott Schoeffel, Esq.

In the past five years or so an increasing number of health insurers have been using "narrow networks" of providers in an attempt to hold down medical costs and insurance premium rates. A key part of the narrow network strategy is to deter use of out-of-network providers, steering patients instead to a comparatively small network of providers where the cost, and possibly the quality, of care can be more closely managed. One method insurers have used to limit out-of-network use has been to terminate, or otherwise penalize, providers whose patients record high out-of-network use.

The Texas Legislature recently adopted legislation to restore some measure of choice for patients enrolled in narrow networks by outlawing a number of tactics preferred provider networks and health maintenance organizations may use to discourage out-of-network use. Texas House Bill 547 enacted a package of amendments to the Texas Insurance Code that safeguard patients' out-of-network benefits in a variety of ways. Under the new legislation, insurers may not terminate, or threaten to terminate, a patient's participation in a preferred provider plan solely because the patient uses an out-of-network provider. The new law also prohibits insurers from terminating a preferred provider's contract solely because that provider's patients use out-of-network providers.

The legislation also protects a preferred provider's ability to inform patients about their out-of-network provider choices. The law declares that insurers may not in any way prohibit, attempt to prohibit, penalize or otherwise restrict a preferred provider from communicating with an insured patient about the availability of out-of-network services under the insurance plan, although the insurer may require certain disclosures about additional patient costs and potential conflicts of interest in connection with the out-of-network referral. Moreover, Texas insurers may no longer require, as a condition of provider payment, that out-of-network providers give their patients a notification form identifying the provider as out-of-network if the form's content, or the notification process itself, is intended to intimidate the patient. Similar provisions in the legislation apply to health maintenance organizations as well.

This new law, which took effect on September 1, 2015, does not apply to Medicaid or child health insurance programs. Still, it offers a bold and intriguing legislative counterpoint to health insurers' growing use of narrow provider networks as well as business practices that may operate to confine patient choice to in-network providers. If Texas House Bill 547 can start to pry open narrow networks in Texas, it may not be long before other states such as California consider adopting similar protections for their insured patients and health care providers.

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consent" to receive debt-collection calls on behalf of TCEP, a third-party creditor.

A third key issue is the scope of the consent. Express consent is limited in scope to the purpose for which it was originally granted. The TCPA does not require that calls be made for the exact purpose for which the number was supplied, but only that the call bears some relation to the product or service for which the number was provided.[10] However, the scope of a consumer's consent depends on its context and the purpose for which it is given.[11] Consent for one purpose does not equate to consent for all purposes.[12]

The FCC's July 2015 Order addresses a number of issues raised by health care providers:

1. **Is consent required for health care calls?** Prior express consent is not required for autodialed, prerecorded voice, or artificial voice calls to a residential line for a health care purpose, but prior express consent is required for such calls or texts to a cellular phone. Calls for telemarketing, solicitation, or advertising content, or which include accounting, billing, debt-collection, or other financial content require prior express written consent.
2. **What is a health care call?** Calls which have a health care treatment purpose include appointment and exam confirmations and reminders, wellness checkups, hospital pre-registration instructions, pre-operative instructions, lab results, post-discharge follow-up to prevent readmission, prescription notifications, and home health care instructions.
3. **What constitutes consent in the health care context?** According to the FCC, the provision of a phone number to a health care provider constitutes prior express consent for health care calls subject to HIPAA by HIPAA-covered entities and business associates acting on their behalf, as long as the calls are within the scope of the consent given, and there has been no instruction to stop.
4. **What if the consumer is unable to give consent?** The FCC noted that if a party is not able to consent because of medical incapacity, prior express consent to make health care calls subject to HIPAA may be obtained from a third party. A caller may make health care calls subject to HIPAA during that period of incapacity, but the prior express consent provided by the third party is no longer valid once the period of incapacity ends. A caller seeking to make health care calls subject to HIPAA to a patient who is no longer incapacitated must obtain the prior express consent of the called party.
5. **What if the consumer is not charged for the call?** An exemption to the consent requirement applies to automated calls and texts to wireless numbers for health care purposes only if the call is not charged to the recipient, including not being counted against any plan limits that apply to the recipient (e.g., number of voice minutes, number of text messages) and the health care provider complies with the following conditions:

   a. voice calls and text messages must be sent, if at all, only to the wireless telephone number provided by the patient;

   b. voice calls and text messages must state the name and contact information of the health care provider (for voice calls, these disclosures would need to be made at the beginning of the call);

   c. voice calls and text messages are strictly limited to health care purposes; must not be for telemarketing, solicitation, or advertising purposes, or include accounting, billing, debt-collection, or other financial content; and must comply with HIPAA privacy rules;

   d. voice calls and text messages must be concise, generally one minute or less in length for voice calls and 160 characters or less in length for text messages;

   e. a health care provider may initiate only one message (whether by voice call or text message) per day, up to a maximum of three voice calls or text messages combined per week from a specific health care provider;

   f. a health care provider must offer recipients within each message an easy means to opt out of future such messages, voice calls that could be answered by a live person must include an automated, interactive voice- and/or key press-activated opt-out mechanism that enables the call recipient to make an opt-out request prior to terminating the call, voice calls that could be answered by an answering machine or voice mail service must include a toll-free number that the consumer can call to opt out of future health care calls, text messages must inform recipients of the ability to opt out by replying "STOP," which will be the exclusive means by which consumers may opt out of such messages; and,

   g. a health care provider must honor the opt-out requests immediately.
6. **What about reassigned numbers?** Callers are liable for automated calls and texts to reassigned wireless numbers when the current subscriber to or customary user of the number has not consented, subject to a limited, one-call exception for cases in which the caller does not have actual or constructive knowledge of the reassignment;
7. **Can a consumer revoke consent?** Consumers may revoke consent at any time and through any "reasonable means."

The FCC's July 2015 Order did not put an end to the matter, however. Shortly thereafter, the FCC issued a correction stating "the rule applies per call and that . . . telemarketers should

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Where these state laws do apply, their lack of uniformity forces companies to develop national regulatory strategies that include flexible business models and advertising disclaimers tailored to differing state requirements. Companies may opt to use two or more business models in order to maximize their profits through direct to consumer sales to the extent it is legally possible. Alternatively, companies may choose to design only one business structure in a manner that complies with the most restrictive state laws, despite the arrangement being the non-preferred option.

These business models frequently include employing or contracting with licensed professionals or telehealth networks, who can provide the professional services associated with the device. Other business arrangements involve direct relationships with licensed practitioners for their use of the devices in their own practices. The models used will vary based upon whether a state has corporate practice of medicine laws that prohibit lay corporations from employing or controlling licensed professionals. *See, e.g.*, California Bus. & Prof. Code, § 2400, New York CLS Bus Corp § 1507.

New medical devices in the ophthalmic industry illustrate the interplay between state professional practice laws and advanced technological devices. Consumers can now take on-line refractive examinations using computers and smartphones (*Opternative*). They can also use handheld devices and a computer and collect and transmit their refractive exam data from their homes, with the help of a technician (*Blink*). Although the devices may be capable of issuing prescriptions based on the consumers' data, the companies enlist licensed vision care practitioners to write the prescriptions that are electronically transmitted to consumers, in order to comply with professional practice laws. In New York, that practice has proven to be insufficient in warding off allegations of professional practice law violations. The New York Optometric Association has requested state regulators to investigate whether Blink's use of unlicensed technicians to help consumers use the handheld devices violates New York's laws.

As an increasing number of devices change the dynamics between consumers, device companies and practitioners' traditional areas of practice, state laws will need to respond to consumer demand for direct device delivery of certain health care services. Until such time as the laws address these new technologies, companies are advised to develop national business and marketing strategies that address professional practice law restrictions and incorporate licensed health professionals into their business models.

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Giving Your Physician Agreements a Check-Up

Andrea Musker, Esq.

On June 9, 2015, the Department of Health and Human Services Office of Inspector General ("OIG") issued a fraud alert regarding physician compensation relationships and potential liability for illegal kickbacks under the federal anti-kickback statute. The federal anti-kickback statute is a criminal statute that prohibits the exchange of any type of remuneration for referral of federal health care program business (42 U.S.C. § 1320a-7b). Physicians and health care providers are often aware of the federal Stark law, which prohibits self-referrals of Medicare patients for certain defined designated health services when the physician has a financial interest, unless an exception applies (42 U.S.C. § 1395nn). However, health care providers should also be cognizant of the requirements of the safe harbors to the federal anti-kickback statute, a criminal statute, when entering into any financial arrangement. The federal anti-kickback statute reaches all referrals or generation of business and is not limited to the referral of designated health services (like the Stark Law).

In its fraud alert, the OIG focuses on suspect medical directorships and office staff arrangements. Compensation to a medical director that accounts for the volume or value of referrals to a facility by the medical director risks violating the anti-kickback statute, as might arrangements where physicians are not actually providing the services described in their agreements.

Whether an anti-kickback statute safe harbor protects a particular agreement from scrutiny depends on the facts of that arrangement. Here are some common red flags in physician agreements:

1. Is the agreement for a term of at least one year? The anti-kickback safe harbors for personal services or management services only apply to arrangements that are captured in a written agreement, signed by the parties, and that last for a period of at least one year.

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not rely on a consumer's written consent obtained before the current rule took effect if that consent does not satisfy the current rule." Then on August 28, 2015, the FCC issued another declaratory ruling to "make clear that a type of fax advertisement –an efax, a document sent as a conventional fax then converted to and delivered to a consumer as an electronic mail attachment is also covered under the TCPA."

The reaction from interested parties has been swift. A number of petitions have been consolidated before the U.S. Court of Appeals for the District of Columbia Circuit. The petitioners challenge the definition of an autodialer, the "one-call" exception for reassigned calls, the definition of the "called party" as the recipient rather than the intended recipient, and the distinction that auto-dialed health care calls to cellular telephone lines require express consent, but those to residential lines do not.

Although there is still confusion about the TCPA, one thing is clear. To avoid committing a "Robo No-No" and the costly TCPA liability that can result, health care providers should update their intake forms and establish clear policies and procedures for obtaining and documenting express consent to contact a patient's cellular telephone. Such procedures can be very important to establish a defense, because the burden to prove compliance with the TCPA lies with the calling party.[13]

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1 Emanuel v. Los Angeles Lakers, Inc., 2013 U.S. Dist. LEXIS 58842 (C.D. Cal. Apr. 18, 2013) (dismissing the plaintiff's TCPA claim where he voluntarily sent a text to the defendant seeking to display the contents of that message on the scoreboard).
2 In re Jiffy Lube Int'l, Inc., 847 F. Supp. 2d 1253, 1259 (S.D. Cal. 2012).
3 Kolinek v. Walgreen Co., Case No. 13-cv-04806 (N.D. Ill.).
4 47 U.S.C. § 227(b)(1)(A)(iii).
5 Satterfield v. Simon & Schuster, Inc., 569 F.3d 946, 954 (9th Cir. Cal. 2009).
6 47 U.S.C. § 227(b)(3).
7 Reardon v. Uber Techs., Inc., 2015 U.S. Dist. LEXIS 94183 (N.D. Cal. July 19, 2015) (holding that a plaintiff who provided her phone number as part of the application process consented to receive Uber's texts about becoming an Uber driver).
8 Thomas v. Taco Bell Corp., 679 (9th Cir. Cal. 2014). See also, In re Jiffy Lube Int'l, Inc., 847 F. Supp. 2d 1253, 1256 (S.D. Cal. 2012) (noting that at least one previous Ninth Circuit case implicitly accepted that an entity can be held liable under the TCPA even if it hired another entity to send the messages).
9 2014 U.S. Dist. LEXIS 3017 (S.D. Fla. Jan. 10, 2014).
10 Hudson v. Sharp Healthcare, 2014 U.S. Dist. LEXIS 87184 (S.D. Cal. June 25, 2014) (Summary judgment granted for defendant and consent for hospital collection calls established where plaintiff voluntarily provided cellular phone number upon admission and initialed next to the cellular telephone number on the form).
11 Kolinek v. Walgreen Co., 2014 U.S. Dist. LEXIS 91554 (N.D. Ill. July 7, 2014).
12 Id.
13 Patten v. Vertical Fitness Group, LLC, 22 F. Supp. 3d 1069, 1073 (S.D. Cal. 2014).

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2. Does compensation vary? Performance- or quality-based incentives that vary might pass muster, as may physician productivity bonuses in connection with employment, but compensation that otherwise varies based on referrals may disqualify the arrangement from safe harbor protection. Compensation must also reflect the fair market value of the services provided.
3. Does the agreement describe all the services provided? The written agreement should completely describe all of the duties and responsibilities of the parties and accurately reflect the expectations of medical directors or other physician contractors. The services must not exceed what is commercially reasonable.

The OIG's fraud alert may mean increased scrutiny and enforcement activity targeting physician arrangements. The alert serves as a reminder to physicians and entities to review existing agreements to ensure they are active and compliant with the safe harbor regulations.

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Drug and Device Companies May Soon Face Less Burdensome FDA Approval Process

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On July 10, 2015, Congress passed H.R. 6, the 21st Century Cures Act, with a bipartisan vote of 344 to 77. The 352-page bill seeks to make the U.S. Food and Drug Administration (FDA) drug and device approval process less onerous to expedite patient access to new treatments and cures. The final bill aims to accomplish this goal through several provisions. During the review of a new drug, the bill requires the FDA to consider patient experience data in the drug's benefits and risks assessment.[1] The bill creates a structured framework to qualify drug development tools, such as biomarkers.[2] The bill also streamlines the institutional review board process for trials that are being conducted at multiple locations in order to eliminate duplication in the review process.[3]

The bill simplifies the review process for new purposes of previously approved drugs. The FDA must establish a program to evaluate the use of clinical data from previously approved drugs to support the potential approval of that same drug for a new purpose.[4] The bill also requires the FDA to establish a streamlined data review program which would authorize the holder of an approved application to submit a summary of clinical data intended to support the approval or licensure of the drug for a new purpose.[5]

The bill seeks to ease the development of new antibiotics by allowing approval of antibiotics for a limited population of patients based on evidence that is currently considered to be preliminary data. This data includes animal and test tube studies and trials on a small number of people.[6]

Medical device companies could also benefit from this bill. The bill clarifies that for FDA approval of medical devices, evidence such as registry data, studies published in peer-review journals, and data collected in countries other than the United States can be considered under certain circumstances.[7] The FDA must establish a program to provide priority review for breakthrough devices.[8] The bill also allows FDA-authorized third parties to certify the safety and effectiveness of device-related changes in lieu of other FDA submission requirements.[9]

Opponents of the bill warn that these changes make America's already relaxed drug and device approval process even less rigorous at the expense of consumer protection. However, supporters point out that the bill was drafted with the close consultation of the FDA, and revisions were made to earlier drafts to accommodate the FDA's concerns regarding safety standards. The bill must now be approved by the Senate, where supporters hope it will go up for a vote this fall.

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1 H.R. 6, 114th Cong. § 2001 (as passed by Congress, July 10, 2015).
2 *Id.* at § 2021. In the context of this section, terms the "qualify" and "qualification" mean a determination by the Secretary of Health and Human Services that a drug development tool and its proposed context of use can be relied upon to have a specific interpretation and application in drug development and regulatory review under the 21st Century Cures Act. Besides biomarkers, drug development tools also include clinic outcome assessments and any other method, material or measure that the Secretary determines aids for purpose of this section. *Id.*
3 *Id.* at § 2261.
4 *Id.* at § 2062.
5 *Id.* at § 2063.
6 *Id.* at § 2121.
7 *Id.* at § 2222.
8 *Id.* at § 2201.
9 *Id.* at § 2221.

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