What's the Worst That Could Happen? Advising Healthcare Clients When the Law Isn't Clear (or When It's Too Clear)

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I. INTRODUCTION

A. Submitted for Your Approval . . .[1]

In the sovereign state of Dystopia, there are few political figures who wield as much clout as Senator Shadrack McGoon, majority leader of the state Senate and a man capable of formidable righteous indignation. The objects of such indignation are many and varied, but one particular public health issue has recently risen to the top of the list.

You see, Senator McGoon is a voluminous consumer of information from outspoken online sources like Whitebart News, the Daily Bawler and numerous Facebook groups, some of which are vaguely associated with Russian trolls. Having studied that information carefully, he has become extremely concerned that vaccines both are inherently dangerous (they cause autism, don't you know, and some of them even contain formaldehyde) and represent a Soviet-style imposition by the government (which, as is well known, is in the pocket of Big Pharma) that interferes with personal autonomy and, for reasons that are not entirely clear, violates the the First Amendment rights of parents.

In light of these concerns, Senator McGoon introduced, and succeeded in having the Dystopia legislature adopt, the "McGoon Fair and Balanced Vaccine Disclosure Act". The act requires that each physician in Dystopia provide certain written disclosures to the parents or legal guardians of minor children at least 24 hours prior to vaccinating those children. The act further provides that physicians who either fail to provide the written disclosures or fail to wait until at least 24 hours after providing the written disclosures to administer vaccines are guilty of a Class C felony (which, under the Dystopia criminal code, is punishable by up to three years' imprisonment and a $50,000 fine for each violation). In addition, the act provides that any physician who is convicted of violating the act will be deemed to have committed unprofes-

[1]A version of the following hypothetical, and some of the discussion elsewhere in this article, appears in different form in William W. Horton & Anjali B. Dooley, "#ItsMyLane: Legal & Medical Ethics When Doctors Speak Out on Public Policy", contained in the program materials from the American Bar Association Health Law Section's 17th Annual Washington Health Law Summit, December 9–10, 2019.

sional conduct under the Dystopia Medical Practice Act and will suffer automatic revocation of licensure.

Specifically, the act requires that each physician must, at least 24 hours prior to administering a vaccine to a minor child, provide the parents with a written notice that states, in this specific language, that:

- Vaccines involve the introduction of toxins and disease-causing substances into your child's system.
- Most people who get diseases in the United States have been vaccinated.
- Many people believe that vaccines cause autism.
- Vaccines have not been proven to be effective against a large number of diseases, including childhood cancers.
- Vaccine research is often paid for by large multinational corporations that expect to profit from it.
- Vaccines often contain substances like aluminum, mercury and even formaldehyde that have been shown to be toxic and even fatal to human beings.

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You are a well-known healthcare lawyer in Areopagus, Dystopia's largest city and a veritable hotbed of free-thinking liberalism in the otherwise very crimson state. Many physicians have come to you for your sage legal advice, and thus it is not a surprise to you when Dr. Lizzie Stephens, a pediatrician in Areopagus, makes an appointment to discuss an urgent legal problem with you. The problem itself is, however, something of a surprise.

First, Dr. Stephens tells you, she has no intention of obeying this ridiculous new law, the McGoon Fair and Balanced Vaccine Disclosure Act. In her view, it represents an impermissible intrusion into the physician-patient relationship. Beyond that, she believes it would require her to give her patients and their parents medically unsound information that might discourage them from getting appropriate care and leave them exposed to all manner of diseases that had been largely eradicated from the United States. Under no circumstances, she tells you, will she hand parents some sort of preprinted card full of lies and half-truths, and she certainly isn't going to tell parents who are in her office ready and waiting to get their kids vaccinated that they have to take this card, leave, and then come back tomorrow

if they still want their kids to have the shots. "That's ridiculous," she says, "Half of them had to take off work to get there in the first place, and they're not coming back another day!"

Offering Dr. Stephens a shot of coconut water, you point out to her that she has just stated an intention to violate a criminal statute, as a result of which she could suffer any combination of jail time, substantial fines, and loss of her medical license if her acts were discovered. Perhaps, you start to suggest, you and she might discuss other ways of addressing the issue before . . . "Of course they'll be discovered!" she says. "Just this morning, I launched a social media campaign to tell people all about the stupidity of Senator McGoon and the legislature, the spinelessness of the Dystopia Board of Medicine, and the relentless ignorance of all the anti-vaxxers out there! I've taken this fight to the people. Now, I just need you to make sure I keep my license and stay out of jail . . .."

B. What Do You Mean You're Not Sure? Aren't You a Lawyer?

When I argue that rules unravel over time, I mean that, using any of these extended definitions of the term [i.e., "rule" refers to both (i) a particular rule of statutory or common law and (ii) "any principle, policy, theory, or other legal argument that can be cited by a party . . . to a case as a reason why the judge or other official decisionmaker should decide the case in favor of that party"], a "rule" becomes increasingly vague, inapplicable, remote, ambiguous, or exception-ridden. This can happen in one of two ways.

First, rules may become more uncertain "on the books." For example, a statute that seemed to mean one thing may be construed by a court to mean something different. Although the court will usually say that it is clarifying the statute, it does not always do so. It may create an exception, an exemption, a privilege; it might construe the rule narrowly to avoid constitutional problems, or broadly to give effect to an unnoticed legislative intent buried in the legislative history. The court's decision becomes a part of the meaning of the rule, so that the rule now becomes more complex—it is a statute plus a judicial decision . . . ..

The "law on the books" may also become increasingly uncertain due to the legislative process itself. Persons disadvantaged by existing rules may lobby to get new statutes passed that create exceptions, exemptions, or privileges, or to get "special

legislation" of other kinds. These also render the law more complex and convoluted . . . .

The second way rules may become more uncertain is in their application. Persons "disadvantaged" by existing rules may modify their activity so that it falls in the cracks between existing rules or comes more ambiguously within any given rule. Thus, although the rules "on the books" remain unchanged, if people change their conduct so that existing rules less clearly apply to what they do, we can say that overall the law has become less certain. . . .

What is really undesirable about uncertain rules of law is that they leave persons unsure of their entitlements while affording unfettered discretion to official decisionmakers. A rule that is close to the 0.5 level [i.e., one as to which it is impossible to make an informed prediction about how a court would rule in a particular matter] . . . makes it impossible or nearly impossible for persons to plan their activities in light of such a rule. The rule points equally to a decision for claimant or for respondent if the activity is challenged in court. The judge is not compelled by precedent or reason to hold either way, a fact that may leave him more susceptible to extralegal influences (bias, prejudice, corruption) that silently could tip the scale. An appellate court also may rule either way, upholding or reversing the judge at its whim. The parties will have no justifiable expectation of a decision one way or the other.

Thus, a major problem with legal uncertainty is that as rules approach the 0.5 level, we may move from a society under law to a regime of official discretion . . . .

—Anthony D'Amato, *Legal Uncertainty*[2]

The modern American medical center has the legal status of a speakeasy because lawless conduct is being ignored. Though illegal, conduct deemed harmless by enforcement authorities is being countenanced. Enforcement authorities refuse to provide legal safeguards because of their perception that such safeguards would insulate abusive as well as appropriate conduct. Prosecutorial discretion—trust us—has replaced the rule of law. Thus, innovative participants in the marketplace can follow the law and be condemned by the realities of the market, or they can participate in the health care speakeasy and hope for the best—a prospect made more risky by the potential availability of private-party (qui tam) actions under the [False Claims Act].

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[2]71 CAL. L. REV. 1, 3–7 (1983) (footnotes omitted).

—James F. Blumstein, *The Fraud and Abuse Statute in an Evolving Health Care Marketplace: Life in the Health Care Speakeasy*[3]

The popular notion of the law is that it is a set of black-and-white rules written down in some authoritative source somewhere, much like, say, the official rules of baseball.[4] Any given course of action is either lawful or unlawful, rendering the actor either blameless or culpable and subject to penalties and punishment. Correlatively, any competent lawyer—at least, it may be grudgingly admitted, any competent lawyer specializing in the relevant area of the law—should be able to analyze any such course of action and advise his or her client whether it is legally permissible to pursue that course.

The rules of professional conduct applicable to lawyers[5] are, to a significant extent, based on the same sort of notion. The Model Rules of Professional Conduct, as adopted by the

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[3]22 AM. J.L. & MED. 205, 224–25 (1996).

[4]*See* OFFICIAL BASEBALL RULES, 2019 EDITION, *available at* https://img.mlbstatic.com/mlb-images/image/upload/mlb/ub08blsefk8wkkd2oemz.pdf. *Cf. Aside: The Common-Law Origins of the Infield Fly Rule*, 123 PA. L. REV. 1475, 1475 (1975) ("The Infield Fly Rule is neither a rule of law nor one of equity; it is a rule of baseball.") (footnotes omitted). The student author of this legendary analysis, not credited in the publication, was one William S. Stevens, who died at the age of 60 after a distinguished career in both the private practice of law and in the administration of continuing legal education programs. *See* William Grimes, *William S. Stevens, 60, Dies; Wrote Infield Fly Note*, N.Y. TIMES, Dec. 11, 2008, at B11.

[5]For purposes of this article, those rules are presumed to be those set forth in AM. BAR ASS'N, MODEL RULES OF PROF'L CONDUCT (2019 ed.) ("Model Rules"). The rules of professional conduct in each state are based, to a greater or lesser degree, on the Model Rules. (California, the last holdout, implemented new rules closely following the structure of the Model Rules effective November 1, 2018. *See* Jaliz Maldonado, *California Aligns New Rules with ABA Rules of Professional Conduct*, NAT'L L. REV., Aug. 29, 2019, *available at* https://www.natlawreview.com/article/california-aligns-new-rules-aba-rules-professional-conduct.) However, there are many state variations—for example, where states have adopted an earlier version of the Model Rules but have not adopted subsequent amendments, or where states have modified the text of particular rules or comments to suit their own preferences. Accordingly, readers are admonished to review the professional conduct rules in effect in their own states rather than relying on the specific text of particular Model Rules cited in this article, which are intended only as general references. The American Bar Association cannot take your license away from you. The state that gave it to you can.

American Bar Association, largely seem based on the implicit premises that (a) a client will present a lawyer with well-defined questions, and (b) the lawyer will know, or at least be able to determine, well-defined answers in the law that are applicable to the questions. Of course, the Model Rules also implicitly assume that the client will tell the lawyer the truth, (mostly) the whole truth and (almost) nothing but the truth, and that the client, having received the lawyer's clear and definitive advice, will act upon it.

Of course, neither of these notions is true in any meaningful sense. As pointed out by Professor D'Amato in his landmark article, "the law"—especially as applicable to a particular client's particular facts—is a shifting, shimmering, evolving thing, not much like a rulebook at all. Even where portions of the law are contained in statutes and regulations that are then published in official and notionally authoritative volumes, the black-and-white words contained in those pages are subject to interpretation, limitation and occasionally even total invalidation by administrative tribunals and the courts.[6] This uncertainty is particularly evident in the context of a highly regulated industry as to which the rules are complex and sometimes contradictory and where the interpretation of those rules is, as a practical matter, largely within the discretion of regulators and prosecutors who are often accountable to different masters, and of courts that often lack relevant industry-specific knowledge.

Such as, for example, the healthcare industry.

There are few industry sectors subject to as many layers of regulatory oversight as the healthcare industry. Within the healthcare services sector alone, institutional providers are subject to regulation by multiple components of the U.S. Department of Health and Human Services, by state regula-

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[6]To give a somewhat extreme example, in 1987 the Alabama Legislature adopted a number of "tort reform" statutes that were subsequently struck down by the Alabama Supreme Court as being violative of the right to trial by jury guaranteed in the state constitution. Nonetheless, despite being unenforceable, those statutes still remain "the law on the books" as part of the Code of Alabama, traps for the unwary researcher who does not check them against the case law. *See, e.g.,* Ala. Code § 6-5-544(b) (invalidated by Moore v. Mobile Infirmary Ass'n, 592 So.2d 156, 164 (Ala. 1991)).

tory and licensing authorities, by the Internal Revenue Service, by the Department of Labor, by local taxing authorities and zoning boards, by federal and state drug enforcement authorities, and so on and so forth.[7] Physicians are subject to other layers of regulation, drug and device manufacturers to yet others, and insurance and managed care organizations to still others. The client evaluating a prospective arrangement or course of action, and the lawyer assisting in that evaluation, must take into account the potential applicability of a wide variety of legal considerations, ranging from mundane (and hopefully straightforward) questions like "Will this enterprise require a county business license?" to more esoteric ones like "Is this an indirect compensation arrangement under the Stark Law and, if so, does it satisfy the extraordinarily confusing exception for indirect compensation arrangements?" One might think that in a well-ordered world, and in light of the importance of healthcare to the nation's citizenry and its economy, at least this complex web of regulation would be well-coordinated. One might think that, but one would be wrong.

For example, a centerpiece of the reform initiatives contained in the Patient Protection and Affordable Care Act[8] was the establishment of "accountable care organizations" ("ACOs"), organized entities that would bring together various combinations of physicians, hospitals, post-acute providers and payors to manage the care of particular Medicare beneficiaries in a coordinated and integrated manner. In return for their success in doing so, ACOs and their participants would share in the savings Medicare realized from such coordination of care. Unfortunately, astute commentators quickly pointed out that many of the economic arrangements among ACO participants necessary to achieve that coordination of care and to promote the expected savings

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[7] *See, e.g.,* JOHN C. GOODMAN & GERALD L. MUSGRAVE, PATIENT POWER: SOLVING AMERICA'S HEALTH CARE CRISIS 290 (1992) ("Consider Scripps Memorial Hospital, a medium-sized (250-bed) acute care facility in San Diego, California. As [a table in the text] shows, Scripps must answer to 39 governmental bodies and 7 nongovernmental bodies, and must periodically file 65 different reports, about one report for every four beds. In most cases, the reports required are not simple forms that can be completed by a clerk. Often, they are lengthy and complicated, requiring the daily recording of information by highly trained hospital personnel.")

[8] Pub. L. 111-148, 124 Stat. 119 (2010).

raised significant compliance risks under the Anti-Kickback Statute,[9] the Stark Law,[10] the antitrust laws and, if the ACO involved any exempt organizations, the tax exemption laws.[11] Ultimately, it was necessary for federal healthcare, antitrust and tax enforcement authorities to issue a series of "waiver" policies to allow ACO participants some measure of security in structuring their arrangements.[12] Even those waivers, however, are of only limited utility; they only apply to ACOs that are "official" ACOs that meet the requirements of participation in the Medicare Shared Savings Program. They do not apply to so-called "commercial ACOs", similar multi-party arrangements formed to contract with private payors,[13] nor do they limit enforcement of state fraud and abuse or antitrust laws or disciplinary actions by state medical board for arrangements that are perceived to violate applicable medical ethics rules.[14]

Beyond the complexity arising from multiple, overlapping

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[9]42 U.S.C. § 1320a-7b(b).

[10]42 U.S.C. § 1395nn.

[11]*See, e.g.,* Molly Gamble & Barton C. Walker, *4 Key Legal Issues for ACOs*, BECKER'S HOSPITAL REV. (Sept. 10, 2012), *available at* https://www.beckershospitalreview.com/hospital-physician-relationships/4-key-legal-issues-for-acos.html.

[12]*See* U.S. Dep't of Health & Human Svcs. Centers for Medicare and Medicaid Svcs. & Off. of Inspector Gen., *Medicare Program; Final Waivers in Connection With the Shared Savings Program*, 76 Fed. Reg. 67992 (Nov. 2, 2011) (OIG/CMS interim final rule with comment period); U.S. Dep't of Health & Human Svcs. Centers for Medicare and Medicaid Svcs. & Off. of Inspector Gen., *Medicare Program; Final Waivers in Connection With the Shared Savings Program*, 80 Fed. Reg. 66726 (Oct. 29, 2015) (final rule); U.S. Fed. Trade Comm'n & U.S. Dep't of Justice, *Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program*, 76 Fed. Reg. 67026 (Oct. 28, 2011); U.S. Internal Revenue Serv., Notice 2011-20, 2011-16 I.R.B. 652 (Apr. 18, 2011); U.S. Internal Revenue Serv., Fact Sheet 2011-11 (Oct. 20, 2011), *available at* https://www.irs.gov/pub/irs-news/fs-2011-11.pdf.

[13]*See, e.g.,* Bingham Greenebaum Doll, LLP, "Commercial ACOs Must Consider Fraud, Antitrust Concerns When Entering Market", https://www.bgdlegal.com/blog/commercial-acos-must-consider-fraud-antitrust-concerns, June 7, 2018.

[14]*See, e.g.,* Martin Merritt, *The Paradox of ACO Waivers of Medical Fraud and Abuse Laws*, physicianspractice.com, July 21, 2013, *available at* https://www.physicianspractice.com/aco/paradox-aco-waivers-medical-fraud-and-abuse-laws.

areas of legal regulation, there is the fact that when healthcare lawyers talk about "compliance with the law", they are also speaking as much or more about enforcement risk as they are about actual black-letter compliance. This has been true ever since the initial articulation of the so-called "one purpose" test in *United States v. Greber* in 1985: "[I]f one purpose of the payment [from a referral recipient to a referral source] was to induce future referrals, the [anti-kickback statute] has been violated."[15] Under such an unforgiving and rigid standard, almost any economically rational arrangement between a referral recipient—such as a hospital—and a referral source—such as a physician—would be illegal, and in fact criminal. And yet, as Professor Blumstein pointed out nearly 25 years ago, such potentially illegal activities go on all the time, in more-or-less plain view of the authorities, because for one reason or another they are deemed unobjectionable, or at least low-risk, in terms of the potential for harm to federal healthcare programs.

An arrangement that fits within an Anti-Kickback Statute safe harbor precisely—precisely—is insulated from review. An arrangement that has received a favorable advisory opinion from the Office of Inspector General of the Department of Health and Human Services (the "OIG") is—as to the specific parties covered by the advisory opinion request, assuming that they have accurately described the arrangement and do not deviate from what they described—insulated from review. But what about an arrangement that nearly fits within a safe harbor, but not quite? An arrangement that is substantially the same as one described in an advisory opinion, but that involves different parties and perhaps deviates in some (perhaps insignificant, perhaps not) particulars? Those arrangements are not insulated from review and even prosecution in any legal sense, and yet on a daily basis healthcare lawyers give their carefully qualified blessings to clients to proceed with just such arrangements,

[15]United States v. Greber, 760 F.2d 68, 69 (3d Cir. 1985). As a side note, this statement was entirely unnecessary dictum in the context of the case; Greber's kickback scheme was blatantly obvious and had been admitted by him in a related proceeding. *See* William W. Horton, *The Past, Present, and Future of the Anti-Kickback Statute: A Practical History*, in HEALTH CARE FRAUD AND ABUSE: PRACTICAL PERSPECTIVES (Linda A. Baumann, ed.) (3d ed. 2013) 965–966 (hereinafter Horton, *Past, Present, and Future*).

because the risk associated with doing so is perceived to be small.

Beyond that, there are arrangements that, for one reason or another, "everyone knows" are unlikely to be challenged even in the absence of a relevant safe harbor, advisory opinion, or other formal guidance. For example, there are numerous inpatient rehabilitation hospitals operated as joint ventures between acute-care hospitals and rehabilitation hospital management companies.[16] Although there is no Anti-Kickback Statute safe harbor that is plausibly applicable to such ventures, no such venture ever appears to have been challenged on the basis that it violates the prohibitions of the statute, and Anti-Kickback concerns do not typically occupy much time in the negotiation of the joint venture terms.[17] Similar types of custom-and-practice analyses predominate in many states that enforce corporate practice of medicine prohibitions, where which management services organization-based workarounds will be deemed acceptable and which ones will not is often more a matter of common lore than common (or statutory) law.

Indeed, this sort of "enforcement risk guidance" is the stock in trade of many healthcare lawyers; were that not the case, a significant number of salutary client ideas would die on the table because of the inability of lawyers to give clean and unqualified opinions on them. That fact, however, raises its own set of risk-analysis challenges. What, for example, is the likelihood that a client whose arrangements are challenged will be able to successfully raise an advice-of-counsel defense when counsel's advice is "Well, this is likely okay, but of course there's no clear precedent to rely on"? And what is the risk that the lawyer, having advised a client on how it might most safely go down an unclear path, might

[16]In the interests of full disclosure, the author spent a goodly chunk of his first 25 or so years in practice helping put just such joint ventures together, and thus does not have an entirely unbiased perspective on the relevant legal analysis.

[17]If the acute-care hospital is a tax-exempt nonprofit, there are of course issues to be considered. There are also potential Medicare reimbursement concerns in some structures. However, assuming that the joint venture is a legitimate one, with each party having capital at risk and participating in investment returns on a basis proportionate to ownership, no one seems to worry much about Anti-Kickback Statute risks in these types of institutional joint ventures.

later be accused of having instead advised the client on how it might most effectively cover up its misbehavior?[18]

This article will offer, by way of illustration, some situations in which healthcare lawyers may be required to give their clients advice in areas where the law is not terribly clear, as well as in areas where the law may appear to be clear but may not be apposite. Thereafter, it will consider some of the rules of professional responsibility that govern how lawyers may provide that advice within the bounds of legal ethics and will propose some practical strategies for how lawyers may walk that tightrope with at least a reasonable measure of safety.

II. HARD CASES MAKE BAD LAW (AND HARD LAW CAN MAKE BAD CASES): SOME KNOTTY PROBLEMS

In order to provide some real-world context to the types of professional responsibility concerns we seek to address here, it is useful to consider some hypothetical situations that raise those concerns. Thus, this section will offer some scenarios that are, of course, purely imaginary and offered solely for illustrative purposes. Of course.

A. Playing the Percentages, Part 1: It's Only a Problem If It's a Problem

The third-party management services contract has been a staple of the healthcare services industry for a long time. An owner/licenseholder of a nursing home, an ambulatory surgical center, or even a hospital wants to avail itself of the expertise of an experienced operator. A hospital wants to outsource the management of a particular department or service to someone with more specialized knowledge in the relevant area. A physician group wants to focus on practicing

[18]Such as, for example, the lawyers indicted in the so-called "Kansas City" case in 1998, who were charged with conspiring with their client to violate the law through the clever device of advising the client what the law required and how to document compliance with it. *See generally* William W. Horton, *In the Eye of the Beholder: Physician Transactions, Professional Responsibility, and the Winding Road from* Anderson *to* Tuomey, in HEALTH LAW HANDBOOK (Alice Gosfield, ed.) (2011 ed.) § 7:2. The lawyers were acquitted at trial.

medicine and desires to off-load the back-office functions to a manager focused on the business and financial aspects of the practice. These are all common arrangements, each of which is replicated throughout the industry on a daily basis.

In most respects, it is not difficult to structure these arrangements so as to meet the Anti-Kickback Statute safe harbor covering management and personal services contracts.[19] Written agreement, signed by the parties, services specified, minimum one-year term—all easy enough. And if folks were willing to agree on a fixed fee arrangement for the services, there would be almost no compliance worries, at least if the fixed fee represented fair market value for the services to be provided and the arrangement were commercially reasonable even in the absence of referrals between the parties.[20]

However, it is significantly more common for these sorts of management contracts to provide for compensation based in whole or in part on a percentage of the net revenues, collections or net income of the entity (or department or service) being managed. Such a percentage arrangement is often desired by both sides of the transaction—the manager wants to ensure that if it does a good job and grows the business of the managed entity, it participates in the fruits of its labor, and the owner of the managed entity wants to ensure that it is not taking on a new fixed cost that will have to be paid each month regardless of the performance of the business. The percentage component may constitute the whole of the management fee, or it may take the form of an incentive bonus or stop-loss adjustment on a fixed-fee arrangement, but one or both parties will almost always want some element of the manager's compensation to be tied to a percentage of revenues or income, and such arrangements are very common.

As a business matter, this often makes eminently good sense. As they say in the strategic consulting game, it "aligns

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[19]42 C.F.R. § 1001.952(d).

[20]More accurately, no compliance worries under federal healthcare-specific laws. If the party engaging the manager were tax-exempt, there would be a need to ensure that the arrangement complied with the private inurement/private benefit laws, and if that party had any outstanding tax-exempt bond financing, then the compensation arrangement under the management contract would need to comply with Rev. Proc. 2017-13.

the interests" of the entity owner and the management company. Indeed, percentage management fees are conceptually somewhat akin to the sorts of risk-sharing arrangements that are increasingly promoted as part of the shift to value-based reimbursement for healthcare services. However, there are at least two significant areas where percentage-based management fees have been called into question by healthcare regulators.

In the context of the Anti-Kickback Statute, the OIG has regularly stated that "[p]ercentage compensation arrangements are inherently problematic under the [Anti-Kickback Statute], because they relate to the volume and value of business generated between the parties, rather than the fair market value of the services provided."[21] The OIG has regarded this as a matter of particular sensitivity where the activities for which the percentage-based compensation is being paid include marketing activities and/or billing activities, the thought process apparently being that the temptation to engage in inappropriate marketing activities or improper billing will be too great if the management company may thereby increase the actual amounts paid to it as management fees.[22]

Now, the trained eye will note that these concerns to some extent beg the question. Obviously, overutilization is a bad thing, and we may concede that the payment of a percentage-based management fee to a manager who actually has significant control over steerage of patients is concerning from an Anti-Kickback Statute perspective. For example, if the operator of a clinical laboratory were to engage an internal medicine physician group to "manage" the laboratory under

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[21]OIG Advisory Opinion 11-17 (Nov. 16, 2011), at 5. *See also, e.g.,* OIG Advisory Opinion 14-1 (Jan. 13, 2014), at 5; OIG Advisory Opinion 98-4 (Apr. 15, 1998), at 5.

[22]*See* OIG Advisory Opinion 98-4 (Apr. 15, 1998), at 5–6; OIG Advisory Opinion 98-1 (Mar. 19, 1998). *See also* OIG Advisory Opinion 03-8 (Apr. 3, 2003), in which the arrangement did not involve a percentage management fee but a per-patient-day fee for the management of an inpatient rehabilitation unit within an acute-care hospital. The OIG, in declining to provide a favorable advisory opinion, noted that the management company would be providing marketing services and stated that "while the per patient per day fee may be reflective of the actual costs incurred [by the management company], it could also simply cloak a success fee."

an arrangement that provided for a percentage-of-collections management fee, the objection to that would be obvious. The only constraint on the actual management fees received by the group would be how many patients of the group had decent coverage for lab tests.

On the other hand, a management company that does not direct or control patient referrals but simply does conventional marketing activities—community outreach to patients and referral sources, health fairs, online and print advertising, etc. – really doesn't seem to present the same sorts of risk. Yes, if the company does a good job of marketing and increases the revenue of the managed entity, then under a percentage fee arrangement, it will make more money than it would if the managed entity's revenues were flat. Indeed, the OIG might even say that the incremental management fee was a "success fee", a concept of which the OIG disapproves. But there does not appear to be anything in the United States Code or the Code of Federal Regulations that declares that success fees are inherently evil, and if the management company does not in fact control or influence (other than by dint of effective marketing efforts) referrals to the managed entity, it is not immediately apparent why paying the company more for better results presents any risk with which the Anti-Kickback Statute ought to concern itself. It is perhaps for this reason that, despite the OIG's oft-stated antipathy toward percentage-fee management contracts, there appears to have been little or no enforcement activity directed against such arrangements in the absence of a specific and fairly direct linkage between referrals originating from the management company or its affiliates and the management fee.

Of course, advisory opinions are not the law, and the OIG has not said (nor does there appear to be any basis in the law for it to say) that percentage-fee management contracts are necessarily illegal per se. Indeed, they remain fairly commonplace. And yet, the OIG has said what it has said, and the lawyer counseling a client on such an arrangement must give some thought to how to advise the client about the risk that any particular percentage-fee contract might expose it to liability, or at least allegations of liability, under the Anti-Kickback Statute.

And concerns in that regard are not limited to federal law

considerations. There are, of course, states which have their own anti-kickback laws. But beyond that, almost every state contains some kind of prohibition on fee-splitting arrangements, wherein a physician or other medical professional pays compensation to a third party (including a management company) that is based on the professional fees collected by the physician.

Concerns with the applicability of fee-splitting restrictions on percentage-fee management contracts are particularly acute in states that enforce the traditional prohibition on the corporate practice of medicine. The conventional workaround for that restriction is what is called a "captive PC"[23] arrangement, in which a physician conducts his or her practice through a professional corporation or professional limited liability company (for purposes of the discussion, the "PC"), which then contracts with a third-party management company to provide substantially all of the services required for the practice other than the actual personally performed professional services. In these structures, the management company will typically be responsible for office and equipment leases, non-physician staffing, marketing, back-office functions, and so on and so forth, in exchange for which the PC will pay a management fee that is ordinarily calculated to strip out from the PC all of its income except the portion necessary to pay physician compensation. That fee is usually based in whole or in part on a percentage of the PC's collections (except in states like New York that affirmatively prohibit such arrangements).

The potential problem with this structure is fairly obvious. A physician's payment to a lay management company that is calculated on the basis of the physician's collections for professional services would, other things being equal, appear to be a classic case of fee-splitting. And yet, as a practical matter, there are many service arrangements with physicians that are calculated on just such a basis, from routine billing and collection services contracts to the sorts of comprehensive management agreements utilized in captive PC structures. Thus, there must be some basis on which to draw a line between permissible contracts and impermissible fee-splitting, right?

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[23]Or "friendly PC".

In a number of states, this distinction is drawn on a case-by-case basis after consideration of the nature of the services provided and the fair market value of those services. For example, California permits, by statute, "payment or receipt of consideration for services other than the referral of patients which is based on a percentage of gross revenue or similar type of contractual arrangement . . . if the consideration is commensurate with the value of the services furnished or with the fair rental value of any premises or equipment leased or provided by the recipient to the payer."[24] By case law, Florida appears to regard percentage management fees as permissible where they do not involve compensation for the referral of patients,[25] but to raise fee-splitting concerns where the services provided include things such as "negotiating and administering managed care contracts and [designing and implementing] an effective public relations program so as to make the public aware of services at the clinic" and "[responsibility] for marketing to the public".[26] However, the Florida Board of Medicine has suggested that the analysis of percentage management fees must also take into account not only the amount of a physician practice's billings, but also the cost of the services provided by the management company.[27] Other states take a variety of positions on what is and is not permissible in the context of

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[24]Cal Bus. & Prof. Code § 650(b). Note the interesting fact that the statute permits only percentage fees based on gross revenues rather than the more typical percentage of net revenues or collections, one of many idiosyncrasies of California's medical practice laws.

[25]Practice Management Associates, Inc. v. Gulley, 618 So.2d 259, 260–261 (Fla. App. 1993).

[26]Gold, Vann & White, P.A. v. Friedenstab, 831 So.2d 692, 694–695 (Fla. App. 2002).

[27]*See* Final Order, In re The Petition for Declaratory Statement of Dr. Gary R. Johnson, M.D., and The Green Clinic, 14 FALR 3935 (Fla. Bd. Med. July 11, 1992), *available at* http://www.floridahealth.gov/licensing-and-regulation/declaratory/_documents/medical/clinic.pdf. Indeed, the declaratory statements on fee-splitting issued by the Florida Board of Medicine in the 1980s and 1990s are a veritable cavalcade of fine distinctions. *See generally* Jeff Cohen, *Fee Splitting: Clearing Up the Confusion*, https://floridahealthcarelawfirmblog.com/2016/04/13/fee-splitting-is-not-just-splitting-hairs/, Apr. 13, 2016; Allen R. Grossman & R. Andrew Rock, *Fee Splitting and the Management of Medical Practices: A History of Board of Medicine Declaratory Statements*, FLA. BAR J. (Apr. 1998) 48, *available at* https://www.floridabar.org/the-florida-bar-journal/fe

percentage-based management fee arrangements, and often those positions are not expressed in statutes or precedential case law but in a variety of medical board opinions, attorney general opinions, administrative rulings and other sources that are frequently difficult to find, inconsistent with each other, not clearly reasoned, or any combination of the foregoing.

And then, there is the Goldilocks problem: when is the porridge too hot, when is it too cold, and when is it just right? While states may make broad general statements about permissible and impermissible percentage fee arrangements—such as, for example, that percentage fees are permissible if reasonably related to the cost of the services provided—there is usually no authoritative guidance or safe harbor on what would be deemed to be a presumptively permissible percentage. May a management fee be equal to 10% of collections? 25%? 75%? The honest answer is usually, "Who knows?"

So, assume that your client is a physician who has been approached by a physician practice management company that wants to take over the non-clinical aspects of her practice in exchange for a fee expressed as a percentage of the practice's net collections. The fee is not tied to specific patient referrals generated, and the management company does not have its own patients to refer. However, the management company's duties will include such things as community outreach, negotiation with managed care organizations, advertising and marketing the practice, and other activities that have the general purpose of increasing patient flow to the practice. Your client wants to know whether entering into this arrangement will cause either or both of the OIG and the state medical board to descend on her.

You know that, were you to take the (impractical under the circumstances) step of seeking an OIG advisory opinion, the OIG would almost certainly give one of those unfortunate opinions that says, essentially, "We can't tell you that we wouldn't go after you on this arrangement because it might involve a kickback, so you've got to ask yourself one question:

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e-splitting-and-the-management-of-medical-practices-a-history-of-board-of-medicine-declaratory-s/.

'Do I feel lucky?' Well, do you, punk?"[28] On the other hand, you know that there is no authoritative precedent out there that holds that an arrangement like this one violates the Anti-Kickback Statute (if the requisite intent were present, of course), and that such arrangements are in fact quite common.

On the state-law front, you know that in your state, the medical board published a declaratory ruling in 1991 that said, with little explanation, that a particular management agreement with percentage-based compensation violated the prohibition on fee-splitting because the management company's enumerated duties included "promoting the growth and expansion of the practice," which ruling has been routinely cited in law review articles and 50-state surveys ever since. However, you also recognize that it's "common knowledge" among practitioners in your state that the medical board has never objected to a percentage fee arrangement unless it involved more than 10% of net collections, and you know that there is no statute or binding case law precedent that speaks to the issue.

What can you advise your client, consistent with your professional responsibility obligations? What should you advise your client, as a practical matter? Do you have legal exposure if your client takes your advice and gets hammered by either the federal or state authorities?

B. Playing the Percentages, Part 2: "EKRA", as in "EKscRuciAting"

Okay, the whole management fee thing is a bit convoluted and arcane. What about your client's marketing staff? They are salespeople. Surely they can be paid on a percentage commission basis, right? That's what salespeople get!

Well, alright, there are some wrinkles to it. The Anti-Kickback Statute says that it is unlawful for anyone to offer, pay, solicit or receive any remuneration "in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or . . . in return for purchasing, leas-

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[28] *Cf.* DIRTY HARRY (The Malpaso Company 1971) (unofficial script available at https://www.scripts.com/script/dirty_harry_6957).

ing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program."[29] A commission paid to a salesperson or marketing employee for recommending the purchasing, leasing, ordering, etc., of an item or service paid for by Medicare or another governmental program would seem to fall into that bucket.

But wait, it's not all bad news. The statute itself provides that it does not apply to "*any amount* paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services",[30] and if that's not enough, there's a regulatory safe harbor to the same effect.[31] So, can an employer pay its salespeople and other marketing employees a percentage commission on the sale of items or services covered by federal healthcare programs? Of course it can, all day long, as far as the Anti-Kickback Statute is concerned.

Now, the OIG and federal prosecutors have construed this statutory exception and regulatory safe harbor to apply narrowly and literally to compensation paid to bona fide employees (commonly referred to as "W-2 employees") and have declined to extend them to compensation paid to independent contractors ("1099 contractors").[32] This is so even where the services provided by the independent contractor are the sorts of sales and marketing services that are in other fields commonly compensated on a commission basis. Indeed, the OIG has repeatedly stated that "any compensation arrangement between a [s]eller and an independent sales agent for the purpose of selling health care items or services that are directly or indirectly reimbursable by a Federal health care program potentially implicates the [Anti-Kickback Statute]" and has repeatedly identified "compensation based on per-

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[29]42 U.S.C. § 1320a-7b(b)(1)(A) to (B).

[30]42 U.S.C. § 1320a-7b(b)(3)(B) (emphasis supplied).

[31]42 C.F.R. § 1001.952(i).

[32]Compensation paid to bona fide employees is reported for federal tax purposes on Form W-2 and is subject to tax withholdings by the employer. Compensation paid to independent contractors is reported for federal tax purposes on Form 1099 and is not subject to employer withholdings; instead, the contractor is responsible for reporting and paying the full amount of federal, state and local income taxes, FICA, FUTA, etc.

centage of sales" as a "suspect" characteristic of an independent contractor sales arrangement that could indicate that the arrangement violates the statute.[33] A number of advisory opinions have expressed the OIG's distaste for percentage compensation arrangements for independent contractors (both sales agents and other persons in a position to make or influence referrals), at least in part because the OIG perceives the seller to have a lesser ability to exercise supervision and control over an independent contractor than an employer would have over an employee, and the Department of Justice has obtained convictions and guilty pleas in connection with such independent contractor marketing arrangements.[34]

This distinction in enforcement policy has had considerable relevance in areas such as durable medical equipment sales and laboratory marketing, where percentage-based commissions are very common as a form of compensation. With the rise in pharmacogenomics and molecular diagnostic testing—services that have to be "sold," as opposed to more standard clinical laboratory tests that are routinely ordered—the risk involved in using independent contractor marketing representatives and sales agents has become a subject of significant interest. Because most independent contractor sales agents are not interested in working for a fixed fee (which would be necessary for the independent contractor arrangement to satisfy the safe harbor for personal services and management contracts),[35] many lawyers have strongly encouraged laboratory clients to move to an employed sales force who could be paid on a commission basis without violating the Anti-Kickback Statute. And slowly, all became right with the world.

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[33] *See, e.g.,* OIG Advisory Opinion 98-10 (Aug. 31, 1998).

[34] *See generally* Jeffrey S. Baird, *Utilization of a 1099 Marketing Rep—Two Recent Cases*, medtrade.com, Feb. 18, 2018, *available at* https://www.medtrade.com/news/general-healthcare/utilization-of-a-1099-marketing-rep-two-recent-cases/; Brown & Fortunato, *1099 Independent Contractor Marketing Reps*, https://www.bf-law.com/1099-independent-contractor-marketing-reps/ (Nov. 3, 2015).

[35] In fairness, the companies that engage such sales agents are typically not interested in paying fixed fees either, because they are sensitive to the risk that they will end up paying fixed amounts to unproductive sales agents who would not have earned equivalent commissions if they were being compensated on a percentage basis.

Until October 24, 2018, the effective date of the Eliminating Kickbacks in Recovery Act of 2018,[36] called "EKRA" when it's at home.

EKRA was a last-minute addition[37] to a broad piece of legislation called "the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act".[38] The SUPPORT Act was intended as a comprehensive measure to address the opioid crisis through, among other things, promoting the availability of opioid treatment, reducing overprescribing and improving measures to detect, prevent and punish illicit drug trafficking.[39] In the context of its adoption, it appears likely that EKRA was intended specifically to provide criminal penalties for "patient brokers who seek profits off of illegal referrals of [substance use disorder] patients seeking the services of a recovery home, clinical treatment facility, or

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[36]Codified at 18 U.S.C. § 220.

[37]*See, e.g.,* Reesa N. Benkoff & Dustin T. Wachler, *EKRA: Enactment and Implications of the SUPPORT Act's New All-Payor Federal Antikickback Law*, ABA HEALTH ESOURCE, Mar. 2019, *available at* https://www.americanbar.org/groups/health_law/publications/aba_health_esource/2018-2019/march/ekra/; Charles C. Dunham, IV, *Sales and Marketing Compliance: New Federal Anti-Kickback Law May Alter How Clinical Laboratories Compensate Sales Personnel*, Epstein Becker Green Health Law Advisor, Nov. 20, 2018, *available at* https://www.healthlawadvisor.com/2018/11/20/sales-and-marketing-compliance-new-federal-anti-kickback-law-may-alter-how-clinical-laboratories-compensate-sales-personnel/.

[38]Pub. L. 115-271, 132 Stat. 3894 (Oct. 24, 2018).

[39]*See generally, e.g.,* Marianna Sotomayor, *Trump signs sweeping opioid bill with vow to end 'scourge' of drug addiction*, https://www.nbcnews.com/politics/congress/trump-signs-sweeping-opioid-bill-vow-end-scourge-drug-addiction-n923976 (Oct. 24, 2018). As a side note, the SUPPORT Act contains within it "sub-acts" designated by some of the most infelicitous short titles imaginable, such as the "Individuals in Medicaid Deserve Care that is Appropriate and Responsible in its Execution Act", the "Responsible Education Achieves Care and Healthy Outcomes for Users' Treatment Act of 2018", the "Medicaid Providers Are Required To Note Experiences in Record Systems to Help In-need Patients Act", and the author's personal favorite, the "Medicaid Institutes for Mental Disease Are Decisive in Delivering Inpatient Treatment for Individuals but Opportunities for Needed Access are Limited without Information Needed about Facility Obligations Act".

laboratory".[40] However, there is effectively no legislative history on EKRA, and its language is much broader than the opioid treatment setting.

EKRA establishes criminal penalties that may be imposed upon:

> whoever, with respect to services covered by a health care benefit program, in or affecting interstate or foreign commerce, knowingly and willfully—
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> (1) solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind, in return for referring a patient or patronage to a recovery home, clinical treatment facility, or laboratory; or
>
> (2) pays or offers any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—
>
> (A) to induce a referral of an individual to a recovery home, clinical treatment facility, or laboratory; or
>
> (B) in exchange for an individual using the services of that recovery home, clinical treatment facility, or laboratory . . . .[41]

"Health care benefit program" is defined to include any public or private third-party payor (i.e., not only Medicare, Medicaid and other federal healthcare programs, but also commercial insurance and managed care plans), and "laboratory" is defined to include essentially all clinical laboratories. Thus, "all referrals for clinical laboratory tests, regardless of payor source, potentially implicate EKRA, even if the tests do not relate to substance abuse testing or treatment."[42] In other words, to the extent it applies, EKRA is an all-payor anti-kickback statute applicable to referrals to any clinical laboratory for any laboratory test.

In the context of compensation payable to sales and marketing personnel, EKRA specifically protects compensation paid by an employer to both employees and independent contractors, but only:

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[40]H. Carol Saul & Genevieve M. Razick, *EKRA: New Kickback Law Creates Risk for Common Medical Lab Marketing Practices*, https://www.jdsupra.com/legalnews/ekra-new-kickback-law-creates-risk-for-91209/ (July 17, 2019).

[41]18 U.S.C. § 220(a).

[42]Saul & Patrick, *supra*.

> if the employee's[43] payment is not determined by or does not vary by—
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> (A) the number of individuals referred to a particular recovery home, clinical treatment facility, or laboratory;
>
> (B) the number of tests or procedures performed; or
>
> (C) the amount billed to or received from, in part or in whole, the health care benefit program from the individuals referred to a particular recovery home, clinical treatment facility, or laboratory . . . .[44]

Thus, taken literally, EKRA would prohibit (and punish as a felony) any commission payment to a person engaged in sales or marketing for a clinical laboratory of any kind, even if that person were a bona fide employee of the laboratory. As a result, EKRA would appear to prohibit such commission-based arrangements in the laboratory context even where they were permitted under the statutory exception and/or regulatory safe harbor under the Anti-Kickback Statute.

The analysis is rendered more confusing by another section of EKRA, which provides that EKRA "shall not apply to conduct that is prohibited under [the Anti-Kickback Statute]".[45] Read in its most logical grammatical sense, that language would suggest that if an activity were prohibited under both EKRA and the Anti-Kickback Statute, EKRA would cease to be applicable to it and the punishment, if any, would be limited to that available under the Anti-Kickback Statute. However, since it appears that the payment of percentage commissions to bona fide employees is not prohibited, but rather is permitted, under the Anti-Kickback Statute, that in turn would mean that such activity would be punishable under EKRA (if it involved a recovery home, clinical treatment facility or laboratory) despite the fact that it would be permissible under the Anti-Kickback Statute. The policy underlying this provision is not readily apparent. Indeed, it would appear more logical if the EKRA provision had said that EKRA would not apply to conduct that was *permitted* under the Anti-Kickback Stat-

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[43] *Sic*; presumably should read "employee's or independent contractor's".

[44] 18 U.S.C. § 220(b)(2).

[45] 18 U.S.C. § 220(d)(1).

ute, rather than prohibited thereunder,[46] but in the absence of any legislative history there is nothing other than logic to support the hypothesis that the "prohibited" language was a scrivener's error.[47]

At the time of this writing, the Department of Justice has proposed no regulations under EKRA, nor has it issued any interpretive guidance that might reconcile the exceedingly confusing differences between EKRA and the relevant statutory and regulatory language and guidance under the Anti-Kickback Statute.[48] Thus, the many clinical laboratories that pay sales and marketing personnel on a commission basis are left in something of a limbo state. Anecdotally, some have begun to shift their commission arrangements to other compensation arrangements that fit within the EKRA exceptions, even though those arrangements are commercially unfavorable; others believe that Congress is likely to amend and clarify the statute and that it is unlikely to be enforced against usual and customary compensation arrangements in the meantime; still others simply lie low and hope something will happen to remove the EKRA cloud that hovers over

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[46] An observation that has been made by others as well. *See, e.g.,* Saul & Patrick, *supra*.

[47] It should be noted that there is another exception in EKRA that is superficially appealing but of little practical utility in the sales commission context. 18 U.S.C. § 220(d)(4) provides that a compensation arrangement does not violate EKRA if it complies with the Anti-Kickback Statute safe harbor for personal services and management contracts. However, since that safe harbor does not protect percentage commission arrangements, it offers no relief in the situation under discussion. As a further example of the curious drafting utilized in EKRA, the exception at 18 U.S.C. § 220(d)(4) only protects, by its terms, compensation arrangements that satisfy the personal services and management contracts safe harbor "as in effect on the date of enactment of this section". Assuming that language would be given literal effect, then even a post-October 2018 change to the safe harbor that specifically permitted percentage compensation arrangements would be disregarded in determining the availability of the EKRA exception.

[48] Although the Anti-Kickback Statute is a criminal statute, it is contained within Title 42 of the United States Code and thus is interpreted by the Department of Health and Human Services, and specifically by the OIG. EKRA is contained within Title 18, the federal criminal code, and thus is interpreted not by federal healthcare regulators but by the Department of Justice, which would also be responsible for any safe harbor regulations and the like.

them, taking cold comfort in the fact that there have thus far been no prosecutions under the statute.

What do you do when a laboratory client asks you to bless its sales commission system? Do you tell them the law is the law and that they need to move immediately to a different, non-percentage-based compensation system that will likely be unsatisfactory both to the client and to its sales force? Do you tell them to ignore, not just a law, but a *criminal* law, because probably nothing bad will happen? What are you even permitted to say at all, ethically speaking?

C. Purt' Near but Not Plumb: The Arrangement That Should Fit within a Safe Harbor, If Only There Were One

Philosophically speaking, regulatory safe harbors are permissive rather than prescriptive. If your client has a situation to which the Stark Law applies, the facts may be complicated, but the ultimate legal issue is pretty simple: either your client's arrangement is in strict compliance with a Stark exception, or it violates the law. However, if your client has a situation to which the Anti-Kickback Statute potentially applies, then strict compliance with a safe harbor will insulate that arrangement from prosecution, but failure to comply with a safe harbor does not mean that the arrangement violates the statute. Indeed, the OIG noted that point in the preamble to the final rule adopting the original Anti-Kickback Statute safe harbors: "The failure of a particular business arrangement to comply with [the safe harbor regulations] does not determine whether or not the arrangement violates the statute because, as we stated above, this regulation does not make conduct illegal."[49]

Although the OIG has declined to recognize a standard of substantial compliance with a safe harbor, as a practical matter that is a test that is often applied by lawyers in advising clients on a particular arrangement—that is, if an arrangement meets the material aspects of a safe harbor but does not fully comply with it, a lawyer may still advise a client that there is little enforcement risk with respect to the

[49]U.S. Dep't of Health & Human Svcs., Off. of Inspector Gen., *Final Rule: Medicare and State Health Care Programs; Fraud & Abuse; OIG Anti-Kickback Provisions*, 56 Fed. Reg. 35952, 35955 (July 29, 1991).

subject arrangement, at least if the noncompliance relates to an aspect of the safe harbor that seems of lesser or more tangential importance.

For example, in 1999 the OIG promulgated a safe harbor for investments in ambulatory surgical centers ("ASCs").[50] The ASC safe harbor is a bit of a curious one, in that it is the only safe harbor that not only does not prohibit a physician investor from being in a position to make referrals to the entity in which the investment is made—here, the ASC – but affirmatively requires that to be the case, and in certain circumstances requires that a minimum volume of referrals be made to that entity.[51] The OIG's rationale for these requirements was that it believed the safe harbor should protect a physician's investment in an ASC where the physician used that ASC as an "extension of [his or her] office"—essentially, that the physician would be actively engaged in performing the types of services provided at the ASC and would not simply be generating investment returns through passive referrals.[52]

The safe harbor protects four (or technically, five) different types of ASC ownership structures: ASCs that are entirely owned by surgeons; ASCs that are entirely owned by physicians practicing in a single specialty; multi-specialty ASCs that are entirely owned by physicians; and ASCs that are jointly owned by physicians and at least one hospital, which may be either single-specialty or multi-specialty.

What the safe harbor does not protect is ASCs that are

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[50] 42 U.S.C. § 1001.952(r).

[51] For surgeon-owned and single-specialty ASCs, each physician investor must have derived at least one-third of his or her medical practice income for the past 12 months from the performance of surgical or other procedures that are on the list of procedures that Medicare will reimburse if performed in the ASC setting ("ASC Procedures"). For multi-specialty ASCs, each physician investor must meet the additional requirement that he or she must have actually performed at least one-third of his or her ASC Procedures during the past 12 months at the ASC in which he or she is invested. These requirements are commonly referred to as the "one-third tests".

[52] *See* U.S. Dep't of Health & Human Svcs, Off. of Inspector General, *Final Rule: Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute*, 64 Fed. Reg. 63518, 63534 to 63539 (Nov. 19, 1999).

jointly owned by physicians and non-hospital management companies that are in a position to make or influence referrals to the ASC. This could be presumed to be a significant problem, since a large number of ASCs are owned by just such joint ventures that include just such management companies (some of which joint ventures include hospital investors as well). However, no one in the ASC chain management company industry seems to be particularly troubled by this lacuna, and there does not appear to have been any reported enforcement action ever taken against an ASC on the basis that its investors included such management companies.[53] Thus, as a practical matter, it appears that a lawyer could reasonably advise an ASC management company client that it appeared unlikely that any enforcement action under the Anti-Kickback Statute would be taken against an ASC joint venture solely because the management company owned an equity interest in the joint venture. There seems to be little reason to believe that noncompliance of that particular sort would be of particular interest to the OIG or other regulatory and enforcement bodies.[54]

On the other hand, other sorts of noncompliance with the ASC safe harbor would appear much more likely to generate

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[53]Many ASCs include in their governing documents the requirement that physician investors meet the applicable one-third tests. One unanswered question is whether ASCs that are non-safe-harbored by reason of having non-hospital management company investors (or for any other reason, for that matter) should impose such requirements, since they involve a requirement of referrals that would ordinarily be prohibited. The author takes the position that it is good to comply with the applicable safe harbor to the extent possible and thus that it is prudent to include such requirements. However, the author has had many arguments over the years with highly reputable healthcare lawyers who assert that if an ASC is outside of the safe harbor by virtue of having non-hospital management company ownership, the ASC should not require compliance with the one-third tests because that could be construed as an impermissible inducement for referrals. The author believes those highly reputable healthcare lawyers are mistaken.

[54]Indeed, in OIG Advisory Opinion 08-08 (July 25, 2008), the OIG issued a favorable advisory opinion with respect to a proposed ASC arrangement that deviated from the safe harbor requirements in numerous respects. One of those respects was that the non-physician investor in the ASC was not a hospital, but rather a health system holding company that owned hospitals, among other things. The OIG apparently did not feel it necessary even to address this distinction, although it discussed the other deviations from the ASC safe harbor in some detail.

enforcement interest—for example, the inclusion of physician investors who were not in a position to perform procedures at the ASC but who could generate referrals to other physicians who could and would perform such procedures.[55] That would fairly obviously deviate from the idea that physician ownership in ASCs was only permissible where the physician owners used the ASC as an extension of their office practices and would pose a non-trivial risk that the opportunity to invest in the ASC was an inducement to the non-surgeon physicians to refer their surgery cases to the surgeon investors. To take an even easier example, consider the safe harbor for personal services and management contracts. It might not be unreasonable to conclude that an arrangement that met all requirements of that safe harbor except that it did not provide for a minimum term of at least one year probably presented little risk of enforcement activity under the Anti-Kickback Statute. On the other hand, that conclusion would seem considerably less reasonable if the arrangement met all requirements of the safe harbor except that it provided for compensation that varied directly with the volume or value of the referrals generated by the contractor. Simply put, this is not a quantitative analysis ("The safe harbor has seven elements, and this arrangement meets five of them; therefore it's probably okay"), but rather a qualitative one: does the deviation from the safe harbor go to a relatively tangential factor, or to a central concern of the Anti-Kickback Statute?

Suppose, then, that you are visited by a new client. The client wants your help in documenting a new joint venture in which physicians from multiple independent practices would jointly own a facility at which a new technology would be deployed to treat patients suffering from a particular condition. The service would not constitute a designated health service under the Stark Law, would not be a service on the Medicare ASC Procedures list, and would be covered

[55] *See* OIG Advisory Opinion 03-05 (Feb. 6, 2003) (declining favorable advisory opinion where physician investor was a multi-specialty group practice that included a large number of primary care physicians); *cf.* OIG Advisory Opinion 07-13 (Oct. 12, 2007) (declining favorable advisory opinion where ASC ownership would include not only ophthalmologists who performed procedures at the ASC, but also optometrists who could not perform procedures at the ASC but who could and did refer cases to the ophthalmologists).

by Medicare and Tricare. Each physician investor would be expected to refer his or her own patients to the facility, but each physician investor would also be actively involved in the hands-on treatment of patients at the facility (either such physician's own patients or patients referred from other sources) and would receive investment returns based on relative ownership interests and not based directly on the volume or value of patient referrals made by that physician.

"So you see, it's like an ambulatory surgical center," the client tells you. But of course, it isn't actually an ambulatory surgical center, and there is no other obvious Anti-Kickback Statute safe harbor. How do you advise your client? Or must you show your client the door?

D. A Very Special Conflict: When Obeying the Law Is Against the Law

A particularly thorny challenge in advising healthcare clients is presented by the recent phenomenon of state legislatures passing more-or-less blatantly unconstitutional statutes that affect the physician-patient relationship in the expectation that a conservative majority on the U.S. Supreme Court will change previously settled law. Typically, those laws are drafted so as to go into effect immediately, or soon after their passage, even if they are clearly unenforceable under existing law, the idea being either that they will be challenged and provide the Supreme Court with a test case or that they will be validated by the Court's decision in a case involving another state's law.

One of the first examples of this type of legislation to draw wide notice was the Florida "Firearm Owners' Privacy Act," passed in 2011.[56] The law, among other things, prohibited licensed healthcare providers from asking patients about their ownership of firearms or ammunition or from entering any information about firearm ownership into a patient's medical record unless it was directly relevant to patient care. The law was specifically aimed at restricting pediatricians from asking their patients' parents about guns in the home (a practice encouraged by the American Medical Association, among others, but which the law's supporters claimed infringed upon the Second Amendment rights of

[56]Fla. Stat. § 790.338.

patients). A federal district court granted summary judgment in favor of the plaintiffs challenging the law (which included the Florida Chapter of the American Academy of Pediatrics, other professional associations, and several individual Florida physicians) and enjoined enforcement of the law. Among other things, the plaintiffs alleged that the statute violated their First Amendment rights. In 2014, a three-judge panel of the 11th Circuit reversed that decision and vacated the injunction.[57] The 11th Circuit granted rehearing en banc, and thereafter found that the content-based restrictions in the act, including the prohibition on asking patients about firearms in the home, were unconstitutional, and those portions of the law were struck down.[58] However, after the initial passage of the law, at least 14 other states introduced similar legislation. None of that legislation has been enacted as of the time of this writing, but the saga of the "gun gag law" indicated that some legislators in some states were quite willing to attempt to limit the ability of physicians and other providers to communicate with their patients based not on the medical appropriateness of such communications but rather because of external political concerns. Physicians who believed that these types of communications were both protected under the First Amendment and professionally appropriate were faced with the choice of obeying a law that they believed to be incorrect and unlawful or disobeying it and potentially being subject to its sanctions.

A more recent phenomenon has brought this choice into even starker relief. Since the *Roe v. Wade*[59] decision was handed down by the Supreme Court in 1973, state legislatures have had very limited ability to restrict the availability of voluntary abortion procedures prior to the time a fetus is

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[57]*See generally, e.g.,* Mobeen H. Rathore, MD, CPE, *Physician "Gag Laws" and Gun Safety*, AMA J. ETHICS, Apr. 2014, *available at* https://journalofethics.ama-assn.org/article/physician-gag-laws-and-gun-safety/2014-04.

[58]*See generally, e.g.,* Rebecca Hershers, *Court Strikes Down Florida Law Barring Doctors From Discussing Guns With Patients*, Feb. 17, 2017, https://www.npr.org/sections/thetwo-way/2017/02/17/515764335/court-strikes-down-florida-law-barring-doctors-from-discussing-guns-with-patient.

[59]Roe v. Wade, 410 U.S. 113 (1973). *See also* Planned Parenthood of Southeastern Pennsylvania v. Casey, 505 U.S. 833 (1992) (modifying standard announced in *Roe*).

determined to be viable. However, with an increasingly solid conservative majority on the Supreme Court since the appointment of Associate Justice Brett Kavanaugh, anti-abortion activists and conservative legislatures believe that there is a significant possibility, if not an outright probability, that the Court will take an opportunity to overturn or at least significantly limit *Roe* in the near future. As a result, several states have adopted highly restrictive new laws on abortion, with the aim that such laws will give the Court an opportunity to act and that such states will have laws on the books and ready to be enforced if and when *Roe* is overturned.[60]

While these laws vary in their details, a number of them impose significant restrictions on physician-patient interactions and the ability of physicians to perform voluntary pregnancy terminations, including criminal penalties. For example, Mississippi's new law prohibits any person from performing an abortion after a fetal heartbeat is detected, subject to limited exceptions. A physician who violates that prohibition may have his or her medical license suspended, revoked or restricted and may be charged with a misdemeanor with the potential for fines and/or jail time.[61] (Previously adopted Mississippi law also includes a number of other restrictions on the availability of voluntary abortions, including a requirement of specific in-person counseling and a 24-hour waiting period between the counseling and the abortion procedure.)[62]

Georgia likewise adopted "fetal heartbeat" legislation, prohibiting abortions (subject to certain exceptions) after there is a detectable human heartbeat, providing that "[a]ny

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[60]*See generally, e.g., Where abortion restrictions stand: The states that have passed laws*, axios.com, Oct., 29, 2019, *available at* https://www.axios.com/abortion-restriction-states-passed-laws-8326c9aa-6631-4bd1-b02b-c6ba6cd0a335.html; Nicole Chavez, *The rising wave of abortion restrictions in America*, cnn.com, May 24, 2019, available at https://www.cnn.com/2019/05/18/us/abortion-laws-states/index.html; Eric Levenson, *Abortion laws in the US: Here are the states pushing to restrict access*, cnn.com, May 30, 2019, *available at* https://www.cnn.com/2019/05/16/politics/states-abortion-laws/index.html.

[61]*See* Miss. Code § 41-41.34.1.

[62]*See generally* Guttmacher Institute, *State Facts About Abortion: Mississippi*, Sept. 2019, *available at* https://www.guttmacher.org/fact-sheet/state-facts-about-abortion-mississippi.

woman upon whom an abortion is performed in violation of this Code section may recover in a civil action from the person who engaged in such violation all damages available to her under Georgia law for any torts", providing detailed and specific requirements for obtaining informed consent for an abortion (including advising patients that the state makes available on a website materials that "describe the unborn child, list agencies that offer alternatives to abortion, and contain information on fetal pain"; although the statutory language is imprecise, it also appears that the abortion provider is required to provide hard copies of this information by personal delivery or certified mail if the woman seeking the abortion—the "female," in the language used by the statute—"chooses to view the materials other than on the website").[63] Ohio adopted a fetal heartbeat bill with requirements somewhat similar to those in the Georgia legislation. The Ohio law provides for civil claims against the performing physician by the woman who obtained the abortion, disciplinary action against the physician, and felony charges against the physician carrying the possibility of imprisonment for up to 12 months and fines of up to $2,500.[64]

Almost certainly the most extreme of these laws was the one adopted in Alabama in 2019. That statute effectively bans all abortions at any time (i.e., even before a fetal heartbeat can be detected), subject to very limited exceptions (serious health risk to the mother (which must be confirmed by a second physician, except in a defined medical emergency); a mental illness where a birth might lead to a woman's death or the death of her child (with confirmation by a psychiatrist); or in the case of fetal anomalies where a child might be stillborn or die after birth). The law provides that physicians who perform abortions may be sentenced to life imprisonment, and physicians who perform "attempted abortions" may be sentenced to up to 10 years in prison.[65]

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[63]H.B. 481, Ga. Gen. Assembly 2019–2020 Reg. Sess., enacted May 7, 2019 as Act 234.

[64]S.B. 23, 133rd Gen. Assembly, Ohio, enacted July 11, 2019.

[65]H.B. 314, 2019 Reg. Sess., Ala., enacted May 14, 2019.

By and large, enforcement of the most restrictive state laws has been enjoined by federal courts.[66] However, a number of these statutes (or related laws previously passed by the same states) include provisions that purport to cause them to take effect immediately upon any overturning of *Roe*. Further, it is not inconceivable that an appellate court could dissolve the injunctions without waiting on Supreme Court review, and it is not entirely clear whether any of these laws would be given retroactive effect if the legal impediments to their enforcement were eliminated. Thus, it is to some extent an open question whether a physician who violates laws of this type, even though they are not currently being enforced and even though they are manifestly unconstitutional unless the Court limits or overturns *Roe*, is exposed to liability under applicable state law.

This same question, of course, might be asked of a physician who violated a state gun gag law, or an anti-vaccine law of the type described in the introduction to this article. How should you advise a client who tells you that he or she intends to break a law (or is already breaking a law) that is likely unenforceable but may not stay that way? What if the client believes sufficiently in the justice of his or her cause that he or she intends to attack the offending law through social media posts?

III. BUT THERE MUST BE SOME RULES ABOUT THIS, RIGHT?

Earlier in this article, we noted that the Model Rules were to a degree limited in their practical application to complex professional responsibility issues, in part because they implicitly rest upon a foundational assumption that "the law" applicable to a given situation is both reasonably well settled and reasonably susceptible of being found. In scenarios like those described, that assumption only gets one so far. Nonetheless, the Model Rules (or more precisely, the variant of the Model Rules that happens to be in effect in the particular jurisdiction with which a particular lawyer is

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[66] *See, e.g., Where abortion restrictions stand: The states that have passed laws, supra;* Molly Olmstead, *Where the Country's Strictest Abortion Bans Now Stand*, slate.com, Oct. 29, 2019, *available at* https://slate.com/news-and-politics/2019/10/alabama-abortion-ban-blocked-strict-laws-status.html.

concerned) are the starting point for any analysis, and a number of them are of potential relevance to the types of questions that have been raised above.

Model Rule 1.2 addresses the basic issue of how authority is allocated between a lawyer and his or her client: "[A] lawyer shall abide by a client's decisions concerning the objectives of representation and . . . shall consult with the client as to the means by which they are to be pursued."[67] In other words, the client gets to decide what the client wants to do, what its goal is, and the lawyer's responsibility is to figure out how to get there from here, at least if the client's objective is a lawful one. And if it's not? The rule tells us that the lawyer "shall not counsel a client to engage, or assist a client, in conduct that the lawyer *knows* is *criminal or fraudulent*, but a lawyer may discuss the legal consequences of any proposed course of conduct with a client and may counsel or assist a client to make a good faith effort to determine the validity, scope, meaning or application of the law."[68] The commentary to the rule goes on to put some meat on those bones:

> [9] [Model Rule 1.2(d)] prohibits a lawyer from knowingly counseling or assisting a client to commit a crime or fraud. *This prohibition, however, does not preclude the lawyer from giving an honest opinion about the actual consequences that appear likely to result from a client's conduct*. Nor does the fact that a client uses advice in a course of action that is criminal or fraudulent of itself make a lawyer a party to the course of action. *There is a critical distinction between presenting an analysis of legal aspects of questionable conduct and recommending the means by which a crime or fraud might be committed with impunity*.
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> [10] When the client's course of action has already begun and is continuing, the lawyer's responsibility is especially delicate. The lawyer is required to avoid assisting the client, for example, by drafting or delivering documents that the lawyer knows are fraudulent or by suggesting how the wrongdoing might be concealed. *A lawyer may not continue assisting a client in conduct that the lawyer originally supposed was legally proper but then discovers is criminal or fraudulent*. The lawyer must, therefore, withdraw from the representation of the client in the matter . . . . In some cases, withdrawal alone might

[67] Model Rules R. 1.2(a).

[68] Model Rules R. 1.2(d) (emphasis supplied).

> be insufficient. It may be necessary for the lawyer to give notice of the fact of withdrawal and to disaffirm any opinion, document, affirmation or the like . . . .[69]

From a healthcare lawyer's perspective, this is an interesting rule. There are many acts (or omissions) that may have serious consequences for healthcare clients but that are neither criminal nor fraudulent (or at least not necessarily so). A Stark law violation involves material penalties for a healthcare provider, but the Stark Law is not a criminal law and does not require that a violation of the statute involve any fraudulent intent; in fact, it is not even necessary to know that one is violating the Stark Law in order to violate it. On the other hand, the Anti-Kickback Statute is a criminal law and a violation of it requires some sort of culpable intent,[70] but it is well established that not all activities that could be characterized as violations of the statute will be subject to prosecution; thus, declining to assist a client in a matter that involves potential violations of the Anti-Kickback Statute but which reasonably appears to be insulated from enforcement activity would seem to be an unduly restrictive reading of Model Rule 1.2(d)'s prohibitions. Indeed, the rule and its commentary expressly contemplate that a lawyer may properly assist a client in exploring the limits of the law and may provide an honest and realistic assessment of the enforcement risk. That is, in fact, something that lots of healthcare lawyers do all day long.

The other side of the coin, as it were, to Model Rule 1.2 is Model Rule 2.1: "In representing a client, a lawyer shall exercise independent professional judgment and render candid advice. In rendering advice, a lawyer may refer not only to law but to other considerations such as moral, economic, social and political factors, that may be relevant to the client's situation."[71] The commentary to that rule provides that:

> [1] A client is entitled to straightforward advice expressing the lawyer's honest assessment. Legal advice often involves

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[69]Model Rules R. 1.2, cmts. [9] and [10] (emphasis supplied).

[70]Exactly what sort of culpable intent, and how much, remains a subject involving some nuance; *see generally, e.g.*, Horton, *Past, Present, and Future*, at 975–965.

[71]Model Rules R. 2.1.

> unpleasant facts and alternatives that a client may be disinclined to confront. In presenting advice, a lawyer endeavors to sustain the client's morale and may put advice in as acceptable a form as honesty permits. However, a lawyer should not be deterred from giving candid advice by the prospect that the advice will be unpalatable to the client.
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> [2] Advice couched in narrow legal terms may be of little value to a client, especially where practical considerations, such as cost or effects on other people, are predominant. Purely technical legal advice, therefore, can sometimes be inadequate. It is proper for a lawyer to refer to relevant moral and ethical considerations in giving advice. Although a lawyer is not a moral advisor as such, moral and ethical considerations impinge upon most legal questions and may decisively influence how the law will be applied.
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> . . .
>
> [5] In general, a lawyer is not expected to give advice until asked by the client. However, when a lawyer knows that a client proposes a course of action that is likely to result in substantial adverse legal consequences to the client, the lawyer's duty to the client . . . may require that the lawyer offer advice if the client's course of action is related to the representation . . . . A lawyer ordinarily has no duty to initiate investigation of a client's affairs or to give advice that the client has indicated is unwanted, but a lawyer may initiate advice to a client when doing so appears to be in the client's interest.[72]

In other words, even though the client has the right to decide what the client wants to do and, in consultation with the lawyer, to determine the lawful methods by which to pursue it, the lawyer has an affirmative duty to bring forth information the lawyer believes is materially relevant to the client's decisions, even where that information goes beyond "technical legal advice" on the letter of the law. The client is entitled to the lawyer's honest, objective judgment applied to the client's situation, and not simply to an abstract proclamation of "the law."

This can be of particular relevance when advising a client on a legally complex plan or strategy, and the appropriate advice may be different in the context of advising a client on how to structure an arrangement as compared to advising a client on how to defend an arrangement that has already been implemented. Consider, for example, the rather

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[72]Model Rules R. 2.1, cmts. [1], [2] and [5].

simplistic situation of a physician-hospital arrangement that complies in all respects with the exception for personal services and management contracts except that the parties never got around to signing an actual, formal contract governing the arrangement. If that arrangement is challenged, the lawyer defending it may well seek to cobble together every possible memo, letter, email or cocktail napkin discussing the terms and signed by one party or the other in order to prove the existence of a "written agreement" in the Stark Law sense of that term. On the other hand, a competent lawyer would never advise either the physician or the hospital on the front end not to bother running up legal fees on having a formal contract signed but rather just to rely on an email chain to establish the written agreement. More broadly, sometimes the best advice a lawyer can give is, "Yes, you can do that and, if you do it all exactly right and in the right order and no one deviates from the plan, then the arrangement works and is legal. But the likelihood of all that happening isn't great, and even if it does, you may have to spend years explaining it to the government because it looks funny."[73]

A third relevant rule is Model Rule 3.1: "A lawyer shall not bring or defend a proceeding, or assert or controvert an issue therein, unless there is a basis in law and fact for doing so that is not frivolous, which includes a good faith argument for an extension, modification or reversal of existing law."[74] As expanded upon in the associated commentary,

> [1] The advocate has a duty to use legal procedure for the fullest benefit of the client's cause, but also a duty not to abuse legal procedure. The law, both procedural and substantive, establishes the limits within which an advocate may proceed. *However, the law is not always clear and never is static. Accordingly, in determining the proper scope of advocacy, account must be taken of the law's ambiguities and potential for change*.
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> [2] The filing of an action or defense or similar action taken for a client is not frivolous merely because the facts have not first

[73] *Cf.* the admonition of Teddy Lewis (played by Mickey Rourke) to Ned Racine (played by William Hurt): "Anytime you try a decent crime, there is [*sic*] fifty ways to [foul] up. If you think of twenty-five of them[,] you're a genius. And you're no genius." LAWRENCE KASDAN, BODY HEAT (Ladd Co./Warner Bros. 1981) (third draft screenplay, at 53), *available at* www.imsdb.com/scripts/Body-Heat.html.

[74] Model Rules R. 3.1.

> been fully substantiated or because the lawyer expects to develop vital evidence only by discovery. What is required of lawyers, however, is that they inform themselves about the facts of their clients' cases and the applicable law and determine that they can make good faith arguments in support of their clients' positions. Such action is not frivolous even though the lawyer believes that the client's position ultimately will not prevail . . . .[75]

This rule, although focused on advocacy, is extremely relevant to the role of the lawyer as advisor as well, at least in the healthcare context. In a field regulated in such a complex manner as healthcare, and one with such ambiguity and uncertainty—indeed, an area where "the law is not always clear and never is static"—even a lawyer providing transactional representation should give some thought as to how the client's activities might later be challenged and to how they could be defended.

There are, of course, numerous other parts of the Model Rules that will have relevance in situations of the type discussed here, but these provide the framework for determining how best to advise a client in an uncertain situation and how far the lawyer may go in navigating the uncertainly before creating undue risk for his or her client and/or for the lawyer personally.

IV. THE ANSWERS ARE IN THE BACK . . . SORT OF

Taking that framework, then, how might we approach advising clients in situations like the examples given above? The following subsections offer some ideas. However, it should be borne in mind that these situations are very fact-dependent, with the relevant facts not necessarily limited to the ones identified here but also including the client's overall compliance profile. That is to say, a client with a well-established, relatively clean track record on compliance issues may sometimes more safely take a more aggressive position on a particular matter than a client that invariably pushes against the outside of the compliance envelope.

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[75] Model Rules R. 3.1, cmts. [1] and [2] (emphasis supplied).

A. Scenario 1: The Percentage Management Fee

In most situations involving percentage management fees and other percentage-based fees, the first goal is, frankly, not to be the nail that sticks up the highest. An arrangement that is consistent with ascertainable market practices is not necessarily a safe and fully insulated one, but there is comfort to be drawn from the fact that there are other folks out there with the same or similar arrangements who are not being prosecuted or excluded. Beyond that, there are some specific steps that can be taken to mitigate risk.

First, determine which laws are applicable to the arrangement. If it falls within the scope of the Stark Law, the client's flexibility is going to be considerably limited, since there is no "substantial compliance" concept under the Stark Law and, in general, the Stark Law is not going to accommodate an arrangement where the compensation varies with the volume or value of referrals or other business between the parties (which a percentage arrangement will inherently do). If applicable state law imposes specific requirements or prohibitions (as in California or New York, for example), the lawyer will want to figure out whether those present deal-stoppers or whether the client's proposed arrangement can be structured to fit within them. If one of the parties has tax-exempt bonds outstanding, the lawyer and the client will need to address the applicability of Rev. Proc. 2017-13.

Assuming those sorts of things don't present impediments, then the question becomes what advice to give with respect to Anti-Kickback Statute compliance, as to which there is unlikely to be any absolute comfort short of obtaining an advisory opinion. A good starting point is to review the relevant advisory opinions with an eye to what sort of safeguards the OIG relied upon in determining to provide a favorable advisory opinion (and what factors specifically concerned the OIG in circumstances where it issued an unfavorable advisory opinion). To the extent similar safeguards can be incorporated into the client's proposed arrangement, that would obviously be a good idea. Beyond that, though, the lawyer and the client should make a realistic assessment of the fraud and abuse risk present in the arrangement and adjust the arrangement as much as possible to mitigate or

eliminate that risk. In rendering advice, the lawyer should, consisent with Model Rule 2.1, consider how the arrangement is likely to be perceived by the OIG or a qui tam relator and how likely it is that there will be some error in implementation of the arrangement that will jeopardize the compliance analysis and advise the client frankly about such things. "This should be permissible if you do everything right, but it's going to be hard to defend if you don't or if the analysis is too complex to be easily explained" is often very good practical advice.

At the end of the day, it is unlikely that the lawyer will be able to give the client absolute assurance that a percentage-fee arrangement will survive scrutiny under the Anti-Kickback Statute, but the lawyer should be able to provide a reasonable and realistic assessment of the likelihood of enforcement activity (accompanied, of course, by appropriate references to the OIG's position that such arrangements are suspect). This is information that will be of practical utility to the client, and is ethically appropriate in the context of Model Rule 1.2(d) and its commentary. It is advisable for the lawyer to record the basis for that analysis either in a written communication to the client or a memorandum to the file, but the lawyer should be careful that such analysis reflects the particular facts provided by the client and that it does not foreclose the ability to make other arguments in defense of the arrangement if it is ever challenged.

B. Scenario 2: EKRA and Sales Commissions

This scenario is conceptually similar to the one just above, but is different in important and meaningful ways. Like the Anti-Kickback Statute, EKRA is a criminal statute, but unlike the Anti-Kickback Statute, it does not have any meaningful body of interpretive guidance behind it, nor does it have any safe harbors other than the limited ones in the statute itself. There is a basis on which a reasonable lawyer can tell the client that, while a particular arrangement might ultimately be determined to violate the Anti-Kickback Statute, it is unlikely that the violation will be addressed through a criminal prosecution. There really is no basis, other than common sense, on which a reasonable lawyer can say that with respect to an EKRA violation.

This is important, because under Model Rule 1.2(d), a

lawyer cannot ethically advise a client to commit a crime or assist a client in doing so. Even though a lawyer might believe for various reasons that enforcement activity based on conventional, market-standard commission compensation paid to W-2 employees was extremely unlikely, it would put the lawyer on ethically shaky ground to advise the client just to ignore the risk of prosecution under EKRA.

In approaching an EKRA analysis of a sales commission arrangement, then, the first step is to determine how the arrangement would likely be treated under the Anti-Kickback Statute if EKRA were not a consideration. If the arrangement involved payments to W-2 employees of the client, then absent some unusual fact pattern it would likely be completely insulated from Anti-Kickback Statute concerns. If it involved payments to independent contractors, there would be greater risk; however, from a realistic perspective, if those payments reflected fair market value commission rates and the independent contractors were simply "traditional" sales representatives and not persons in a position that gave them particular influence over patient referrals—like doctors, or doctors' office staff, for example—then it would be reasonable to conclude that the risk of enforcement action under the Anti-Kickback Statute was fairly low.

If the assumption is that EKRA will be interpreted on a basis consistent with the current official interpretations and prevailing wisdom on the Anti-Kickback Statute, it would be reasonable to conclude that, at least as to employed sales and marketing personnel, market-standard commission arrangements would not violate EKRA. However, there is nothing in the statute to suggest that, and there is really no external guidance on which to rely (at least as of the time of this writing). On the other hand, a client might well conclude that the practical risk of going forward on that basis was small, and there is reason to think that that is not an irrational position.

On the current state of the law, the prudent course would seem to be for the lawyer to say, essentially, "I have to tell you that this is a criminal statute, and I cannot advise you to continue with a commission arrangement that appears on its face to violate the statute. But I can tell you that there has not been any enforcement activity under the statute so far, and you might well decide as a business matter that you

are prepared to take the risk that the statute could be enforced against you." That would be consistent with the lawyer's obligations under Model Rule 1.2(d) and also with the obligation to provide candid advice under Model Rule 2.1. However, it should be clear that such advice is limited to the W-2 employee context, and the client should be appropriately cautioned about the greater risk inherent in commission sales arrangements with independent contractors.

C. Scenario 3: The Notional Safe Harbor

Consider now the circumstance where the client's business arrangement falls outside of a safe harbor but has characteristics that seem consistent with the analytical approach taken in the safe habor—e.g., the deal that is "just like an ambulatory surgical center."

Once again, the first step is to make sure that the arrangement doesn't run afoul of the Stark Law or other potential traps outside the Anti-Kickback Statute. Assuming that to be the case, the appropriate advice requires careful, close analysis. For example, in our hypothetical "quasi-ASC" arrangement described above, the starting point should probably be a good hard look at how well the arrangement matches up to the "theology" of the ASC safe harbor. Objectively, is this arrangement one as to which the physician investors are truly using the joint venture facility as an extension of their practices? Are they providing hands-on patient care, or is their involvement predominantly through passive referrals that generate income from ancillary services or other non-personally-performed services? Is the service being provided one as to which there are natural impediments to overutilization (part of the idea behind the ASC safe harbor is that a surgeon is less likely to scrub up and cut on someone for no reason just to get a piece of the facility fee than he or she would be to order some additional tests or imaging work from a diagnostic facility in which he or she was an investor)? What role does government reimbursement play (because realistically, the OIG and the Department of Justice are less likely to devote resources to scrutinizing a facility for which the vast majority of services being provided are covered by commercial insurance or private pay)?

Moving beyond that abstract analysis, are there advisory opinions or court cases involving factually similar arrange-

ments? What about the factors listed in the OIG's "recommended prelimnary questions" for advisory opinion requests[76]—how does the arrangement stack up against those? What safeguards can be put in place to minimize the risk of abuse?

It is, of course, always safe lawyering to tell a client, "Gee, there's no safe harbor that covers what you want to do and so I can't tell you it's okay (unless you want to get an advisory opinion, of course)," but that is not always good lawyering. As the commentary to Model Rule 2.1 tells us, "Purely technical legal advice, therefore, can sometimes be inadequate." In context, that statement seems to refer to situations where a client's course of action may be technically defensible but may expose the client to issues based on the political, ethical or moral context in which the technical legal advice will be applied. However, it also refers to those situations where purely technical advice may be excessively conservative and may unncessarily discourage a client from pursuing a course of action as to which there is a good-faith legal position to take.

In these sorts of situations, the lawyer must balance prudent conservatism (and appropriate disclosure of the risks to the client) with informed creativity. The Anti-Kickback Statute is an intent-based statute, and the safe harbors are not exclusive as far as ways to comply with it go. A client is entitled to our caution, but is also entitled to our objective and prudent analysis as to how a door that seems closed might safely be opened. Again, this is a qualitative test and not a quantitative one; an arrangement that satisfies six components of a seven-component safe harbor may still be highly unsafe if the one noncompliant piece goes to the heart of the safe harbor. But there is room for some disciplined creativity in analyzing Anti-Kickback Statute issues, and lawyers are ethically permitted to employ that creativity (with appropriate disclosures to the client as to the risks involved).

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[76]U.S. Dep't of Health & Human Svcs., Off. of Inspector Gen., "Recommended Preliminary Questions and Supplementary Information for Addressing Requests for OIG Advisory Opinions In Accordance With Section 1128D of the Social Security Act and 42 CFR Part 1008", *available at* *https://oig.hhs.gov/fraud/docs/advisoryopinions/prequestions.htm*.

D. Scenario 4: Which Law Should We Violate?

This last scenario—the somewhat hypothetical anti-vaccine conflict of our introduction and the very real-world conflict between existing Supreme Court precedent and recent anti-abortion legislation—is in many respects the most difficult discussed here, because there is simply not much way to affect the odds through analysis. Either *Roe* will be overturned or limited or it won't. Either the courts will uphold challenges to the sort of anti-vaccine legislation hypothetically describe here or they won't. Unlike the situation where the law is unclear because of nuance and interpretation, in those sorts of cases there is a much greater likelihood of ending up with a clear answer that will either be the one your client wanted or it won't.

As contemplated by Model Rule 1.2(d) and Model Rule 3.1, it is always permissible to assist a client in exploring the limits of existing law and advocating for changes in those limits, even where the outcome is far from certain, provided that the lawyer has appropriately advised the client of the risks and obtained the client's informed consent. At the same time, even though under Model Rule 1.2(a) the client retains the ultimate authority to decide what objectives it wants to pursue and which of the available methods to get there it wants to use, the lawyer has a duty to help the client analyze the risks entailed by those decisions in an objective manner, taking into account the social, political, moral and practical contexts in which the decisions are being made.

Thus, in our hypothetical example, you should affirmatively confirm that your client Dr. Stephens understands the material legal risks associated with her particular course of action, and to the extent you have a basis for doing so, you should also advise her of the factors you think may materially affect how she pursues that course. For example, although there is nothing particularly illegal about criticizing the law (and/or the lawmakers) through social media and even announcing one's intent to challenge the law, that approach may expose the client to greater legal risk and impair her ability to defend her actions if they are later challenged. It is appropriate, and indeed desirable in many cases, for the lawyer to say to the client, "Hey, let's think about what you're trying to accomplish here and whether what you're doing is more likely to get you closer to your goal or further away from it."

This is no one right answer in situations of this type. In fact, there often does not seem to be any right answer; in this polarized political environment, it is not even possible to be sure that, in the event of a major change in prevailing law, the courts and legislatures will provide for a reasonable transition period for those affected to adapt to the changes. Presumably, even if the Supreme Court were to, say, overturn *Roe*, the specific requirements of various state restrictions would be challenged in court, providing some breathing space. Ultimately, though, the only course open to lawyers advising clients in these situations is just to lay the risks out as clearly as possible, analyze them, and develop a strategy that will provide the client with as much protection as is feasible under the circumstances—which may or may not be much protection at all.

E. A Brief Note on Self-Preservation

To a greater or lesser degree, all of the scenarios described above involve lawyers advising their clients on unclear situations in which the client may end up with regulatory, civil or criminal exposure. One known side effect of that phenomenon is that the lawyer who has carefully explained to the client how to minimize the risk of getting in trouble to the extent possible may instead be accused of having conspired with the client to develop an evil scheme, or at least to cover one up.

The best defense against that is usually going to be a good file with documentation of the relevant legal analysis and of material communications with the client. No one likes doing "CYA memos," and of course one wants to maintain the documentation with appropriate privilege and work-product legends. But one key in dealing with these sorts of issues where the law is simply not clear is being able to show that the lawyer took a reasonable, prudent and thorough approach to the legal analysis and advised the client on that basis—and ideally to be able to show that the client took a reasonable and prudent approach to following it. Ultimately, the advice given may have been wrong; in that event, it will be of great benefit to both lawyer and client to be able to show that, although wrong, it was reasonable and that it was given and followed in good faith.