Introduction and Scope of Article

The federal Anti-Kickback Statute\(^1\) ("AKS") and regulations issued by the Office of Inspector General ("OIG") of the Department of Health and Human Services ("HHS") provide for exceptions to the criminal liability imposed under the AKS.\(^2\) Although the exceptions are called "exceptions" in both the statute and regulations,\(^3\) they are commonly referred to as "exceptions" when speaking of the statutory provisions and "safe harbors" when speaking of the regulatory provisions. Despite the seemingly simplistic concept of the exceptions and safe harbors – meet their requirements and an arrangement is immune from enforcement – in practice whether their protections actually exist is not always clear.

This article covers in depth the following three topics: (1) whether meeting the stated requirements of the statutory exceptions and regulatory safe harbors provides absolute protection from prosecution and administrative sanctions or whether a party must also prove the lack of intent of an illegal inducement if an arrangement is challenged; (2) the scope of the statutory exception and regulatory safe harbor for remuneration paid to an employee; and (3) the differences between certain of the statutory exceptions and their corresponding regulatory safe harbors and whether the OIG has statutory authority to engraft additional conditions onto a statutory exception.\(^4\)

Does Meeting the Conditions of a Statutory Exception or Regulatory Safe Harbor Provide Absolute Protection?

The popular, and, in the author’s opinion, correct view is that if all of the listed requirements of a statutory exception or regulatory safe harbor are met, the parties to the subject arrangement are immune from prosecution under the AKS and administrative sanction under the Civil Monetary Penalty ("CMP") Statute,\(^5\) regardless of what their intent may be.

The purpose of the exceptions and safe harbors is to provide assurance

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Contemplating Well-Being (or, secure your own oxygen mask before assisting others…)

We are moving into the holiday seasons. The holidays can be a mixed bag. They bring celebrations and festive gatherings with family and friends. They can also bring excess of food and drink, family tensions, and the stress of trying to have a good time while also perhaps having to complete a complex year-end transaction or respond to government demands dropped on a client the day before a holiday. It is timely that the ABA and the Health Law Section have recently launched two new initiatives focusing on health and well-being.

The ABA Commission on Lawyer Assistance Programs (“CoLAP”) has been around a long time. CoLAP’s mission is “to assure that every judge, lawyer and law student has access to support and assistance when confronting alcoholism, substance use disorders or mental health issues….” CoLAP recently cosponsored studies with the Hazelden Betty Ford Foundation and documented the alarming extent to which lawyers and law students grapple with mental health and substance use disorders. In August 2016, CoLAP joined with a collection of entities from within and outside the ABA to create the National Task Force on Lawyer Well-Being (the “Task Force”). A year later the Task Force culminated its work by publishing its report, The Path to Lawyer Well-Being: Practical Recommendations for Positive Change, available on the ABA website at:

https://americanbar.org/content/dam/aba/administrative/professional_responsibility/lawyer_well_being_report_final.authcheckdam.pdf

Following publication of the Task Force’s report in August 2017, current ABA President Hilarie Bass created the Working Group to Advance Well-Being in the Legal Profession (the “Working Group”). This Working Group includes representatives from law firms, lawyer assistance programs and malpractice insurance carriers. The focus of the Working Group is to create model policies for addressing substance use disorders and mental health issues, and then to make them available to law firms and other employers in the legal profession.

Meanwhile, the Health Law Section (“HLS”) expanded our attention to these issues. The HLS was already active in this area through the Substance Use

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from prosecution or other sanctions. Given that intent is subjective and difficult to measure, this makes sense. What is the point of saying that a safe harbor applies unless there is intent to induce referrals? It is not as though the AKS would prohibit certain types of arrangements even absent intent, so what good are the safe harbors unless they immunize arrangements even if there may be intent? For example, a discount given by a merchant to a customer presumably is for the very purpose of incentivizing the customer to purchase from the merchant. The same holds true when a vendor or other entity gives a discount to a healthcare provider or supplier for an item or service that is used in the treatment of patients – including federal healthcare program patients. However, in enacting the statutory exceptions Congress in effect said that it was not worried about certain types of arrangements even if there is intent to induce orders or referrals because federal healthcare programs will benefit. In authorizing the Secretary of HHS to promulgate regulatory safe harbors, Congress stated that the Secretary was to “specify[]” payment practices that shall not be treated as a criminal offense. Congress did not say that the Secretary was to specify payment practices, that, in the absent of intent to induce referrals, would not be treated as a criminal offense.

Guidance published from the OIG is consistent with the view that if all of the listed requirements of a safe harbor are met it is irrelevant whether one or more of the parties to the arrangement had the intent to induce referrals. In the preamble to the 1991 final rule promulgating the original 10 safe harbors, the OIG stated that “[i]f a person participates in an arrangement that fully complies with a given provision, he or she will be assured of not being prosecuted criminally or civilly for the arrangement that is the subject of that provision.” This is a clear statement that the protection of the exceptions and safe harbors exists irrespective of intent provided that their stated requirements are met. Even clearer are the OIG’s statements that the statutory exceptions and regulatory safe harbors “immunize” arrangements that might otherwise violate the AKS. Because intent is necessary for a violation of the AKS, to say that a safe harbor immunizes an arrangement that might otherwise violate the AKS is equivalent to saying that if the safe harbor is met, intent does not matter. Also, in various Advisory Opinions, the OIG reviews the requirements of the applicable safe harbor, and, where the requirements are met, it says simply that the safe harbor is met – it does not say that the safe harbor is met if there is no bad intent.

Note that the safe harbors say that conduct within the four walls of a safe harbor is not remuneration. That is, each of the safe harbors starts with the introductory language “As used in section 1128B of the Act, ‘remuneration’ does not include . . . .” Once something is not remuneration it does not matter whether there is an intent to induce referrals. If a hospital tells a physician it wants the physician to send more referrals, but does not offer any remuneration (and let us say for the sake of argument that the hospital makes clear it will not provide any remuneration), there cannot be an AKS violation. And that is true whether the hospital expresses a good reason as to why it wants the physician to refer more (e.g., it has just brought on a great surgeon), a not so good reason (e.g., the hospital executive will get fired if the census remains low) or no reason at all. Remuneration is an essential component in the statutory language.

Unfortunately for providers and suppliers and others subject to the AKS, however, there are reports of at least a few Assistant United States Attorneys (“AUSAs”) leveraging settlements on the basis that the exceptions and safe harbors do not apply if there is intent of an illegal inducement. Note that whereas the OIG has the delegated authority from the Secretary to issue monetary and other sanctions under the CMP Statute, including sanctions for violations of that section of the CMP Statute that prohibits kickbacks that are illegal under the AKS, criminal prosecutions under the AKS itself are within the sole authority of the Department of Justice (“DOJ”).

Surprisingly, there are very few judicial pronouncements that the safe harbors immunize conforming arrangements from prosecution. Although it is not clear whether any court has held that an arrangement that is squarely within the confines of a safe harbor nevertheless fails to meet that safe harbor if there is intent to induce referrals, as discussed below at least two courts have said in dicta that formal compliance with a safe harbor is not enough – there must also be no intent to induce referrals. Moreover, at least one court has held that a “sham” arrangement that “nominally” meets a safe harbor’s requirements does not get that safe harbor’s protection.

In United States v. Shaw, the district court appears to have taken the view that the absence of intent of an illegal inducement is necessary to fit within the statutory exceptions and regulatory safe harbors. At one point in the decision, the court states:

All of these cases confirm that the issue for a jury to decide, when faced with a defendant whose contention is that the defendant is not criminally liable under the statute due to the “discount exception,” is whether the reason for offering or accepting the “discount or other reduction in price” was to induce

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referrals of or be reimbursed for federal health care program business. It may be the case that one piece of evidence to weigh when considering whether defendant acted with the requisite intent is whether the “discount or other reduction in price” was passed on to the Medicare or Medicaid program. It also may be the case that the profit motive was so strong – the defendant was so severely in debt or the amount of profit was so enormously high – that a jury could infer that profit motive supports an inference of willful and knowing purpose to induce referrals of or be reimbursed for federal health care program business.16

Shaw’s statement that intent has some role to play in determining whether a safe harbor is met is curious given its quotation elsewhere in the opinion of the OIG’s statement from the 1994 proposed rule that the safe harbors “describe payment practices that would be prohibited, where the unlawful intent exists, but for the safe harbor protection that has been granted.”17 Shaw’s statement is even more curious given that it seems self-evident that the intent behind any discount from a seller to a buyer, in the context of a healthcare transaction or any other transaction, is to induce the buyer to purchase the discounted product or service.

Despite what appears to be a clear misstatement of the law, Shaw’s position has been repeated in at least one other decision. In U.S. ex rel. Westmoreland v. Ament, Inc.,18 the court stated “[i]f the requisite intent to willfully or knowingly solicit or offer a kickback is present, formal compliance with a safe harbor is not sufficient to avoid liability under the Anti-Kickback Statute.”19 The Westmoreland court’s statement is also puzzling, given that the court also recognized that “[a] number of statutory and regulatory safe harbors protect certain business arrangements that might otherwise violate the [AKS].”20 Because the only way that an arrangement “might otherwise violate” the AKS is through intent, this statement is tantamount to an acknowledgement that the statutory exceptions and regulatory safe harbors offer protection irrespective of intent, or put another way, that they apply even if there is intent to induce referrals. So why would the Westmoreland court follow this statement with one that says “formal compliance” (whatever that is) with a safe harbor is not enough to avoid a violation of the AKS?

In U.S. v. Goss,21 the court held that even if the safe harbor for lease arrangements was met, that would have protected only a bona fide lease arrangement, and that because there was sufficient evidence for the jury to find that the lease arrangement was a sham, the safe harbor was inapplicable. The facts in the case were unfavorable for the defendant. The defendant made a deal with someone who turned out to be an FBI informant; the deal appeared to be a bargain for rent in exchange for referrals. According to the court, it was clear that the jury believed that the defendant received the rent and referred two patients in return for the rent.

There is a common-sense appeal to the court’s reasoning, but ultimately it is unsatisfactory. Although the idea of withholding safe harbor protection for arrangements that are sham arrangements may seem uncontroversial, the underlying question is what is a sham arrangement? The answer cannot be any arrangement the real purpose of which is to induce referrals, because if that were true it would exclude employee marketing arrangements and discounts, both of which are protected by statutory exceptions and regulatory safe harbors. Maybe the answer is that a sham arrangement is any arrangement that is ostensibly for one purpose (e.g., a lease) but whose real purpose is to induce referrals. But that approach still has the significant problem of removing the bright line, objective test of whether the criteria of the safe harbor are met and instead injecting a measure of subjective intent into the analysis. If a hospital, which is in need of space, leases space from a physician at fair market value rent, and the rent is fixed instead fluctuating up or down depending on the volume or value of referrals, why should the hospital have to worry whether the government will question whether the purpose – or at least one purpose22 – of the arrangement was to induce the physician to refer patients to the hospital? It is small comfort that the government would have to prove intent, because, given the tremendous penalties, it is fairly easy for the government to leverage a settlement. And if one purpose of the lessee hospital truly was to induce referrals, so what? Where is the harm in an arrangement for space that is needed by the lessee, is for fair market value, and at a fixed amount?

Note the qualifier “which is need of space” in the hypothetical lease arrangement. One of the requirements in the safe harbors for space and equipment lease arrangements is that the rental be for commercially reasonable purposes. If, as what may have been in the case in Goss, the lessee does not really need to rent space but is instead leasing the space from a referral source (even at fair market value), the arrangement is not commercially reasonable but for the referrals, and it would fail the safe harbor on that ground alone. In other words, it may not have been necessary for the Goss court to have ruled that the safe harbor was not available because the purpose of the arrangement was to pay for referrals, if the defendant had failed to prove that the arrangement was commercially reasonable.

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How Safe are the Safe Harbors?

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The commercial reasonableness requirement in the safe harbors for space and equipment leases and personal services and management contracts grew out of the OIG's concern that parties could game the safe harbor requirements by entering into "sham transactions." In the original Federal Register publication of the safe harbors, the OIG stated that "sham rental agreements in which remuneration is exchanged for property that does not exist or space which is not used are among the most egregious kickback arrangements. We have become aware of office rental arrangements in which the 'space' rented may not be large enough or otherwise suitable to perform any services for which rent could legitimately be paid." This concern led to a proposal in the 1994 proposed rule to "clarify" the original 10 regulatory safe harbors. There the OIG proposed a new section 1001.954, which would have provided that "[a]ny transaction or other device entered into or employed for the purpose of appearing to fit within a safe harbor when the substance of the transaction or device is not accurately reflected by the form will be disregarded, and whether the arrangement receives the protection of a safe harbor will be determined by the substance of the transaction or device." The OIG described a sham transaction as one "where there is no intent to have the space or equipment used or the services provided."

However, in the final rule, the OIG did not finalize the proposed new regulatory section but instead added a commercial reasonableness requirement to the safe harbors for space and equipment leases and personal services and management contracts. It explained that the "commercially reasonable business purpose" test was intended to preclude safe harbor protection for arrangements in which a party rented more space or equipment, or purchased more services than it needed from a referral source.

The OIG's approach of requiring that an arrangement be commercially reasonable is far preferable to the approach in U.S. v. Goss. Commercial reasonableness is susceptible to proof by objective facts and expert opinion, and thus the OIG's approach provides comfort both to parties that want to be certain that safe harbor protection will not be denied simply because the government believes there was intent to pay for referrals, as well to the government, which wants to avoid extending protection to sham arrangements.

Intent Built into the Safe Harbor Requirements

Thus far, this article has dealt with the question of whether "bad intent" can be used to defeat safe harbor protection notwithstanding that all of the requirements of a safe harbor have been met. One should recognize, however, that for better or worse, the absence of bad intent is itself a requirement of the safe harbor in the case of "swapping." In other words, a few of the safe harbors incorporate a requirement that a discount or other remuneration is not given by X to Y in order to induce Y to purchase other goods or services from X.

The term "swapping" may have made its first appearance in Advisory Opinion 99-2. There, an ambulance supplier offered a discount to a skilled nursing facility ("SNF") for the SNF's Part A business (which would not be billable to Medicare as it is included in a SNF's prospective payment), but offered no discount to the SNF for its Part B business (which would be billable to Medicare by the ambulance supplier). The OIG denied protection under the safe harbor for the (questionable) reason that a "discount" as defined in the safe harbor did not include a reduction in price applicable to one payor but not to Medicare or a state healthcare program. It then concluded that it would not issue a favorable advisory opinion because the facts and circumstances may have suggested that the purpose of the discount was to induce the SNF to steer Part B business to the ambulance supplier. In the 1999 clarification of the original safe harbors, the OIG stated that swapping arrangements "essentially shift costs to Federal health care programs," and its concern with cost shifting was behind the 1999 rule's exclusion from the definition of "discount" "[s]upplying one good or service without charge or at a reduced charge to induce the purchase of a different good or service, unless the goods and services are reimbursed by the same Federal health care program using the same methodology" (the so-called bundled discount rule). However, although a seller's discount to a buyer on product X is certainly intended to induce purchases of product X, why does it necessarily follow that the discount is also intended to induce the purchase of product Y? If the terms of the written agreement provide that the discount on product X is contingent upon a purchase of some many units of product Y, that is clear enough, but suppose there is no such provision in the written agreement and suppose further there is no evidence of an unwritten side agreement for a contingency. Because a party seeking to invoke the protection of a safe harbor has the burden of proving compliance with the safe harbor, and the OIG does not have the burden of showing that a safe harbor is not met, parties to a discount arrangement would have the burden of proving a negative, i.e., that there was no intent to induce purchases of product Y through the discount on product X. The only effective way a seller can be certain that it receives the protection of the discount safe harbor with respect to an item that is discounted to a buyer is to ensure that the buyer purchases no other items from it unless that item is also discounted.

The requirement that there be no intent to induce other business is not unique to the discount safe harbor. Two of the managed care safe harbors contain the requirement that a party must not give or receive remuneration continued on page 6
in return for or to induce the provision or acceptance of federal healthcare program fee-for-service business.\textsuperscript{31}

The managed care safe harbors are largely a creature solely of regulations,\textsuperscript{12} so if the OIG wishes to place a no swapping condition in them, it should be entitled to do so, even if by doing so it injects some measure of uncertainty as to whether an arrangement meets a safe harbor. However, the situation with the discount safe harbor’s non-applicability to bundled discounts is arguably different. As discussed below, the discount safe harbor narrows the statutory exception (which contains no restriction on bundled discounts) and there is a significant question as to whether the OIG has the authority to do so.

Deeming Something to Be Additional Remuneration That is Outside a Safe Harbor

Another way that the OIG precludes protection of a safe harbor that is seemingly on point and satisfied is to declare that there is additional remuneration between the parties that falls outside of any safe harbor. Specifically, in several Advisory Opinions the OIG has taken the position that one party providing another party an opportunity to generate a fee or realize a profit is remuneration that is not covered under any safe harbor.\textsuperscript{33} This position has particular (and maybe sole) applicability to the personal services and management contracts safe harbor.\textsuperscript{14} Because the personal services and management contracts safe harbor is strictly a creature of regulations, the OIG is free to restrict it as it sees fit. But beyond denying safe harbor protection for some arrangements and creating uncertainty of safe harbor protection for other arrangements, giving legal effect to the OIG’s position that the opportunity to generate a fee is a form of remuneration within the meaning of the AKS would subject some “conduct” to the AKS that might otherwise fall outside the statute. As discussed below, the OIG may not have statutory authority to define “remuneration.”

The Scope of the Statutory Exception/Regulatory Safe Harbor for Employees

Unlike the situation with some statutory exceptions (as discussed in the next section), the statutory exception for remuneration paid to employees is essentially mirrored by the regulatory safe harbor. The statutory exception says that the AKS 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.\textsuperscript{35} The regulatory safe harbor provides:

As used in section 1128B of the Act, “remuneration” does not include any amount paid by an employer to an employee who has a bona fide employment relationship with the employer, for employment in the furnishing of any item or service for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs. For purposes of paragraph (i) of this section, the term employee has the same meaning as it does for purposes of 26 U.S.C. 3121(d)(2).\textsuperscript{36}

Thus, the statutory exception uses the terminology “provision of covered items or services” whereas the regulatory harbor speaks of “furnishing of any item or service” for which payment may be made by a federal healthcare program. The difference, if any, between “provision” and “furnishing” is immaterial.

The exception and safe harbor are relatively simple and broad, and do not even require that the remuneration be fair market value. Despite the broad language of the exception and safe harbor, however, there are two potential dangers for parties that wish to claim their protection. First, the parties run the risk that the remuneration could be determined to have not been paid to a bona fide “employee” and second, the remuneration could be determined to have not been paid for a purpose that is covered by the exception or safe harbor.

Who is An “Employee”?\textsuperscript{38}

In the statutory exception, Congress refers to an “employee” with a “bona fide employment relationship,” without defining either term. In the 1991 final rule promulgating the safe harbor, the OIG stated that it was adopting the definition of “employee” as contained in the Internal Revenue Code ("IRC")\textsuperscript{37} and as interpreted by the Internal Revenue Service ("IRS") in its regulations and program instructions.\textsuperscript{38} Indeed, the text of the regulatory safe harbor specifically includes the IRC’s definition of employee. Irrespective of whether the OIG is owed any deference for its interpretation of the statutory exception,\textsuperscript{39} it seems unassailable that by “employee” Congress was referring to the master-servant relationship as understood by the common law (and which relationship is adopted by the IRC).\textsuperscript{40} In Nationwide Mutual Insurance Company v. Darden, the Supreme Court applied the doctrine that, where Congress uses a term that has a settled meaning under common law, a court must infer, unless the statute otherwise dictates otherwise, that Congress meant to incorporate the established meaning of that term.\textsuperscript{41} The Court held in Darden that because “employee” was not defined in the Employee Retirement Income Security Act (“ERISA”), Congress was presumed to have used the term to mean the common law master-servant relationship.\textsuperscript{42}
According to the Supreme Court, when applying the common law definition, control is probably the most important factor.\footnote{43}

In United States v. Robinson\footnote{44} the court found that the defendant was not a bona fide employee due to, in part, lack of sufficient control by the defendant over the manner and means of the work performed by the workers.\footnote{45}

What are the Proper Purposes for Which Payment May Be Made?

Some uncertainty has persisted with respect to the meaning of “any item or service for which payment may be made in whole or in part.” The OIG has stated on several occasions that the safe harbors protect payments for items and services other than those directly billable to federal healthcare programs. For example, in the 1999 final rule clarifying the original safe harbors, the OIG stated that the safe harbor could be used to protect compensation under a medical director agreement, and, of course, medical director services are administrative services related to the furnishing of professional services but are not the actual furnishing of such services. Likewise, in Advisory Opinions 04-11 and 04-19, the OIG stated that malpractice premium support could be protected under the employee safe harbor.\footnote{46}

The OIG has gone further and stated that the safe harbor protects payments for marketing. In the 1991 final rule establishing the employment safe harbor, the OIG noted that “[t]he proposed exception for employees permitted an employer to pay an employee in whatever manner he or she chose for having that employee assist in the solicitation of program business and applied only to bona fide employee-employer relationships.”\footnote{47} This was the position that the final rule adopted. In response to a commenter that stated that independent contractor salespersons paid on a commission basis should come under the protection of the employee safe harbor, the OIG disagreed and said that “[w]e are confident that the employer-employee relationship is unlikely to be abusive, in part because the employer is generally fully liable for the actions of its employees and is therefore more motivated to supervise and control them.”\footnote{48} The OIG then followed up this response with the response (made to a commenter that suggested that healthcare providers should not be able to refer patients to other healthcare providers within their own offices because abuse could be worse than when individuals or entities make referrals to outside sources) that “[t]he exception for bona fide employment relationships is clear on the face of the statute, and we are not free to ignore that statutory mandate.”\footnote{49} Thus, the OIG appears to have taken the position that sales and marketing arrangements paid on a commission basis are immune from prosecution if they involve employees.

On the other hand, in a 1992 letter from the OIG to the IRS, the OIG stated in a footnote that:

We would also note that while the anti-kickback statute contains a statutory exemption for payments made to employees by an employer, the exemption does not cover any and all such payments. Specifically, the statute exempts only payments to employees which are for “the provision of covered items or services.” Accordingly, since referrals do not represent covered items or services, payments to employees which are for the purpose of compensating such employees for the referral of patients would likely not be covered by the employee exemption.\footnote{50}

Some courts have adopted a narrower view than what appears to be the OIG’s more liberal position (the 1992 letter to the IRS notwithstanding). These courts have held that for the safe harbor to apply, the remuneration must be made to the employee for the purpose of furnishing or providing covered items or services payable under Medicare or other federal healthcare programs, and must not be made for referring patients while employed by an entity that is in the business of furnishing covered items or services. For example, in United States v. Starks,\footnote{51} two individuals were paid for referring patients to a corporation that operated treatment programs for drug addiction. Although they referred patients, they did not personally provide medical services. The court indicated that it did not believe the defendants were bona fide employees, but also said that even if the individuals were bona fide employees, the safe harbor was inapplicable because they “received payment . . . only for referrals and not for any legitimate service for which the Hospital received any Medicare reimbursement.”\footnote{52} See also United States v. Luis\footnote{53} (safe harbor protects payments “made to the employee for furnishing or providing covered items or services or for items or services payable under Medicare,” citing United States v. Starks, and also stating it was irrelevant whether nurses were bona fide employees paid for “covered items or services” because the payments to them were, at least in part, for their illegal patient referrals).\footnote{54} See also United States v. Borrasi\footnote{55} (finding that if some portion of a payment is for referrals, the employee safe harbor will not apply.)

Other courts have taken a broader view of the safe harbor, with some criticizing or distinguishing Starks and Borrasi. For example, in United States v. Halifax Hosp. Med. Ctr.\footnote{56} the government contended that an incentive bonus paid to the doctors was paid, at least in part, to induce referrals. The government argued that any payments for referrals were illegal kickbacks under the AKS regardless of the amount and regardless of whether the payor, the hospital, employed the payee-physician; it contended that the incentive bonus constituted illegal

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remuneration because the payments were derived from a bonus pool that was comprised of profits from the doctor’s referrals to the hospital’s outpatient services and not on the physicians’ “furnishing of any items or service for which payment may be made in whole or in part under Medicare.”

The Halifax Hospital court disagreed. It concluded that to accept the government’s argument would result in the rule swallowing the exception:

Simply stated, the Bona Fide Employment Exception provides that the normal prohibition on payments to induce referrals does not apply where the payments are made to a (for lack of a better word) legitimate employee, 42 U.S.C. § 1320a-7b(b)(3). The Relator would change that to read that the prohibition on payments to induce referrals does not apply where the payments are made to a legitimate employee unless they are payments to induce referrals. The exceptions set forth in the Anti-Kickback Statute and accompanying regulations provide immunity from prosecution for behavior that might have violated the Anti-Kickback Statute. State v. Harden, 938 So. 2d 480, 488-89 (Fla. 2006). The Relator’s interpretation of the Bona Fide Employment Exception would eviscerate it.

Notably, the Halifax court did not discuss or even cite Starks, which is binding law in the Eleventh Circuit.

In United States ex rel. Wall v. Vista Hospice Care, a relator alleged that the hospice defendant violated the AKS by paying employed salespeople and other staff for meeting certain admissions and census targets. In ruling that the payments were protected by the employee safe harbor, the court agreed with Halifax’s reasoning, and added that:

[t]he statutory exception applies to payments for employment in the provision of covered services, not for providing covered services. 42 U.S.C. 1320a-7b(b)(3); see Hericks v. Lincare, Inc., 2014 U.S. Dist. LEXIS 39706, 2014 WL 1225660, at *14 (E.D. Penn. Mar. 25, 2014) (rejecting the argument that the bona fide employee safe harbor did not apply to cash bonuses for referrals paid to employees because bonuses were not “for employment in the provision of covered items or services,” finding that “the [defendant’s] employees [were] employed in the provision of covered items and services” regardless of the specific task compensated by the bonuses). On its face, therefore, the exception protects payments to employees of entities in the business of providing covered services of hospice care, not only for specific direct patient care for which bills can be submitted to Medicare.

The Vista Hospice Care court then turned its attention to the regulatory safe harbor and said that the OIG’s statements in the preamble to the 1991 final rule, mentioned above, supported the position that the protection of the safe harbor is not restricted to payments for the provision of covered items or services. The court concluded that “[a] contrary reading would make all payments to hospice providers’ sales, marketing, and other staff for involvement in patients securing hospice services from their employer illegal for Medicare providers, leaving such providers unable to promote their businesses by rewarding employees based on success.” The court was not impressed with the Starks decision, saying that Starks engaged in no substantive analysis of the safe harbor, “and commented on the ‘covered items or services’ clause without relying on it – the defendants in that case clearly were not bona fide employees, clandestinely receiving checks or cash for their referrals in parking lots to avoid detection.” Nor did the court have kind words for the Borrasi decision, which it said it agreed with the Crinel decision (discussed below) focused on the wrong statutory provision (i.e., the substantive prohibition on illegal inducements) and did not give independent meaning to the safe harbor. According to the Vista Hospice Care court, the Borrasi court’s reading of the statute allows the rule to swallow the exception.

In United States ex rel. Hericks v. Lincare, the relator alleged that, in violation of the AKS, Lincare directed its employees to induce physicians and patients to generate referrals for the provision of medical equipment and services by Lincare, for which Lincare then sought reimbursement under federal health insurance programs. In response to Lincare’s reliance on the employee safe harbor, Hericks claimed that the safe harbor was not applicable because the employees were paid for referrals and not for furnishing services. The court agreed with Lincare, however, that, under Hericks’s reasoning, all payments to sales representatives who sell healthcare goods and services would be improper because those payments would result from referrals.

A case whose holding is in between the narrow and broad readings of the employee safe harbor is the aforementioned United States v. Crinel. There the court posited that:

At one extreme, Defendants argue the safe-harbor provision creates a blanket exception for all Medicare referral fees paid by an employer to a bona fide employee. At the other extreme, the Government argues the payment of Medicare referral fees never falls under the safe-harbor provision, even if made to a bona fide...
employee. Neither of these interpretations is persuasive.

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If an employee refers a patient who is actually eligible for Medicare and receives medically necessary services, the employer may provide appropriate compensation in the form of a referral fee. If, on the other hand . . . an employee receives a referral fee from its employer/co-conspirator as part of a scheme to provide benefits to individuals ineligible to receive them, the safe-harbor provision is not applicable. The Court believes this interpretation best harmonizes all provisions of the anti-kickback statute and accords with Congressional intent.65

It is unclear what the eligibility status of the patient or whether the services in question are reasonable and necessary have to do with anything. Putting that aside, the Cline court’s position, that payment to an employee for referrals is not protected by the exception and safe harbor if the payment is for an improper purpose, has a certain appeal to it but has two obvious defects. First, it injects a measure of intent into what is supposed to be a black-or-white, check-the-box type of analysis. That is, it leaves the conclusion of whether compensation paid by the employer to the employee meets the safe harbor up to the determination – from some type of adjudicator – of whether the employer had some type of intent to induce referrals. Worse, it requires the adjudicator to distinguish bad intent versus acceptable intent. That is, one can presume that an employer who pays an employee salesperson a commission on sales of its product intends to incentivize the salesperson to sell more of its product than the salesperson might otherwise sell if he or she was paid a flat salary, but, assuming for the moment that that is “acceptable intent,” where does one draw the line between that type of intent and “unacceptable intent”?

Second, Congress’s and the OIG’s rationale in promulgating the employee statutory exception and regulatory safe harbor may have been that the employer could be presumed to exercise some degree of control over the employee, but the text of the exception and the safe harbor makes no mention of supervision, let alone predicates the availability of safe harbor protection on there being adequate supervision (whatever that means) of the employee. There is a difference between (1) Congress or an agency presuming that a certain fact (here, adequate supervision) will likely be present due to certain circumstances (here, the employer/employee relationship) and thus feeling comfortable with enacting or promulgating a per se rule, and (2) Congress or the agency requiring proof of such fact in order for the rule to apply. Requiring proof of a predicate fact may have the advantage of avoiding abuse of the rule, but it also may have the disadvantage of causing uncertainty as to when parties may rely on the rule and conduct themselves accordingly, because the parties may not know how the rule will be applied or that it will be applied correctly and consistently. The Cline court’s approach unwisely and improperly second guesses Congress’s and the OIG’s policy decision to create a per se rule devoid of intent.

Does the OIG Have Statutory Authority to Engraft Additional Conditions Onto the Statutory Exceptions for Protections Against Fraud and Abuse, or Must the OIG Take the Statutory Exceptions as it Finds Them?

The question of whether the OIG has the authority to narrow the scope of a statutory exception when promulgating a corresponding regulatory safe harbor has arisen most often in connection with the exception/safe harbor pertaining to discounts. Before addressing the question of whether the OIG has the statutory authority to narrow the discount exception or other exceptions, and putting aside whether the concept of either the statutory exception or regulatory safe harbor is anachronistic in light of federal programs no longer paying based on cost,66 one must address the preliminary question of whether the OIG has in fact narrowed the scope of the discount exception. The OIG has said that it has not. In the 1999 clarification to the original 10 safe harbors, the OIG said that “it continues to be our position that the regulatory safe harbor protects all discounts or reductions in price protected by Congress in the statutory exception (see 59 FR 37206),” that “the regulatory safe harbor expands upon the statutory safe harbor by defining additional discounting practices not included in the statutory exception that are not abusive,” and that “the regulatory safe harbor both incorporates and enlarges upon the statutory exception.”67

A fairer statement, however, is that, except for extending protection for discounts to beneficiaries, the safe harbor narrows the statutory exception. The statutory exception is short and broad, stating only that the AKS does not apply to “a discount or other reduction in price obtained by a provider of services or other entity under title XVIII or a State health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under title XVIII or a State health care program.”68 In other words, any reduction in price (whether it be termed a “discount,” “rebate” or otherwise), obtained by any entity (be it a provider, supplier, manufacturer or whatever) is outside the statute if it is disclosed and accounted for. Thus, (except for specifically covering discounts to beneficiaries, which is relatively unimportant

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given that beneficiaries are rarely implicated in kickback schemes) the regulatory safe harbor really does not include “additional discounting practices not included in the statutory exception.” At best, the regulatory safe harbor protects some discounting practices that are not explicitly mentioned in the statutory exception (but neither are such practices prohibited by the statute), and to the contrary, the regulatory safe harbor narrows the statutory exception in several ways. For example, the safe harbor: (1) covers only certain types of entities, and (2) defines “discount” in such a way that it (a) places significant restrictions on bundled discounts, and (b) excludes altogether from its protection payments in cash or its equivalent, and discounts given to commercial payors if they are not also given to federal healthcare program payors.

Likewise, the statutory exception for remuneration paid by a vendor (e.g., a manufacturer or distributor) to a group purchasing organization (“GPO”) is relatively short. The statutory exception requires only that the GPO have a written agreement with each member of the GPO, which specifies the amount to be paid by the vendor to the GPO, which amount may be a fixed amount or a fixed percentage of the value of the purchases made by each member, and where the member is a “provider of services,” the GPO discloses, in such form and manner as the Secretary requires, to the provider of services and the Secretary the amount received from each vendor with respect to purchases made by or on behalf of the provider of services. The regulatory safe harbor, however, does not extend protection to a GPO whose members are either wholly-owned by the GPO or subsidiaries of a parent corporation that wholly owns the GPO.

Turning to the question of whether the OIG has statutory authority to narrow the scope of the statutory exceptions, a basic proposition is that, generally, agencies have no authority to interpret criminal statutes. According to the Sixth Circuit in Esquivel-Quintana v. Lynch:

In 227 years and counting, the federal courts have never presumed that, when an ambiguity arises in a criminal statute, the congressional silence signals that Congress wants an executive-branch agency to fill the gap. For all of the theories of Chevron that have filled the U.S. Reports and the Federal Reporter, to say nothing of the law journals, the idea that Chevron is a tool for construing criminal statutes has yet to make an appearance. That is because criminal statutes “are for courts, not for the Government, to construe.” Abramski v. United States, 134 S. Ct. 2259, 2274 (2014). The doctrine does not give the Department of Justice (or for that matter any other federal agency) implied gap-filling authority over ambiguous criminal statutes.

Otherwise, that would leave this distasteful combination: The prosecutor would have the explicit (executive) power to enforce the criminal laws, an implied (legislative) power to fill policy gaps in ambiguous criminal statutes, and an implied (judicial) power to interpret ambiguous criminal laws. Cf. The Federalist No. 47, at 297-99 (James Madison) (Clinton Rossiter ed., 1961). And it would permit this aggregation of power in the one area where its division matters most: the removal of citizens from society. The plain language of the first sentence of section 14(a) which states, “Any practices specified in regulations pursuant to [sec. 14 of Pub. L. 100-93] shall be in addition to the practices described in subparagraphs (A) through (C) of section 1128B(b)(3).” This sentence led some commenters to conclude that our regulatory authority does not permit us to refine or clarify the statutory exceptions.

Response: We believe that these commenters have misconstrued the intent of this sentence. The plain language of the first sentence of section 14(a) of Public Law 100-93 requires the Secretary to promulgate regulations “specifying payment practices that shall not be treated as a criminal offense under section 1128B(b) of the Social Security Act and shall not serve as the basis for an exclusion under section 1128(b)(7) of such Act.” We believe that the second sentence, which was quoted by...
many commenters, requires us to add to the exceptions provided in section 1128B(b)(3) of the Act. But we do not believe the intent of this sentence is to prohibit us from interpreting statutory terms used in these exceptions. The clear congressional intent behind the development of these safe harbor provisions is to define innocuous arrangements that should not be prosecuted, including the statutory exceptions. We believe it is in the public interest to provide the health care community with our interpretation of the meaning of certain important statutory terms, for example, “appropriately reflect” in the discount exception or “bona fide employment relationship” in the employee-employer exception.24

There are some problems with the OIG’s response. First, there is a disconnect between the comment and the response. Whereas the commenters questioned the authority of the OIG to narrow the scope of the statutory exceptions and in particular the discount exception, the OIG responded that the commenters were questioning whether it had the authority to refine or clarify the statutory exceptions, and stated that it is in the public interest to provide the health care community with the OIG’s interpretation of certain terms. Regardless of whether it is in the public interest to know the OIG’s thoughts about certain statutory terms, where is the grant of statutory authority to define such terms, and to define them in binding regulations? Section 14(a) of Pub. L. 100-93 does not speak to the OIG developing rules to interpret the statutory exceptions, but rather requires the Secretary to issue regulations that “shall be in addition to” the statutory exceptions.25 Moreover, even assuming that section 14(a) of Pub. L. 100-93 was intended to grant the Secretary the authority to interpret statutory terms,26 where is the authority to go beyond mere interpretation and narrow the scope of the statutory exceptions? In light of judicial hostility of giving any deference to an agency’s construction of a criminal statute, it is unlikely that a court would find that the OIG was given specific authority in the AKS to limit the statutory exceptions.

But is specific authority set forth in the AKS needed? As the OIG has recognized, Congress placed the AKS in title XI of the Social Security Act:

The Secretary is vested with the authority to make and publish rules, not inconsistent with the Social Security Act, necessary to the efficient administration of her functions under [section 1102(a)] of the Social Security Act (42 U.S.C. 1302). The anti-kickback statute, including all exceptions thereto, are codified as part of the Social Security Act.27

At first blush this may seem like a powerful argument in support of the idea that the Secretary, through the OIG, has the authority to gap fill with respect to the statutory exceptions. As the OIG’s language above recognizes, however, the statute limits the Secretary’s authority to that which is “necessary to the efficient administration of the functions with which [the Secretary] is charged under this Act.”28 The question is thus begged, is the Secretary charged with interpreting and narrowing the statutory exceptions under the AKS, as the Secretary sees fit?29

The very few reported decisions that speak directly to the question of whether the regulatory safe harbors supersede corresponding statutory exceptions have answered the question in the negative. In United States v. Shaw,30 the court found that the statutory exceptions and corresponding regulatory safe harbors were separate authorities and that the defendant should be allowed to rely on either the discount exception or the safe harbor; however, the court provided no analysis as to why it reached that conclusion.31 In Klaczak ex rel. United States v. Consol. Med. Transp.,32 the court stated that a certain letter from an ambulance supplier “does not appear to be a correct statement of the law or the facts. For example, it seemingly confuses the requirements for the ‘safe harbor’ exception with the statutory exception for discounts – the latter does not require that Medicaid or Medicare are offered the same discounts.”33 As in Shaw, however, the court gave no analysis as to why, apparently, the regulatory safe harbor did not supersede the statutory exception.

If the OIG has Statutory Authority to Interpret the AKS, Does its Interpretations Deserve Deference?

Apart from the question of whether Congress delegated any authority to the Secretary to interpret the AKS, it seems well settled that in any challenge to the OIG’s interpretation courts would not give Chevron deference.34 And it may be that they would not give any lesser degree of deference.35 And if the government gets no deference as to its interpretation of the AKS, it effectively renders moot the question of whether Congress delegated any authority to the Secretary to interpret the AKS.

Under the rule of lenity, in construing an ambiguous criminal statute, courts resolve the ambiguity in favor of the defendant.36 As the D.C. Circuit explained:

That is to say, the law of crimes must be clear. There is less room in a statute’s regime for flexibility, a characteristic so familiar to us on this court in the interpretation of statutes entrusted to agencies for administration. We are, in short, far outside Chevron territory here.37

The Supreme Court has also weighed in:

The law in question, a criminal statute, is not administered by any agency but by the courts. It is entirely reasonable and understandable that

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federal officials should make available to their employees legal advice regarding its interpretation; and in a general way all agencies of the Government must interpret it in order to assure that the behavior of their employees is lawful – just as they must interpret innumerable other civil and criminal provisions in order to operate lawfully; but that is not the sort of specific responsibility for administering the law that triggers Chevron. The Justice Department, of course, has a very specific responsibility to determine for itself what this statute means, in order to decide when to prosecute; but we have never thought that the interpretation of those charged with prosecuting criminal statutes is entitled to deference. 88

A good and comprehensive synopsis of the law on the lack of deference given to agency construction of criminal statutes appears in a recent D.C. District Court opinion. There the court observed that:

The Supreme Court recently observed that it “ha[s] never held that the Government’s reading of a criminal statute is entitled to any deference,” United States v. Apel, —— U.S. ——, 134 S.Ct. 1144, 1151. Instead, “[w]hether the Government interprets a criminal statute too broadly ... or too narrowly ... a court has an obligation to correct its error.” Abramski v. United States, —— U.S. ——, 134 S.Ct. 2259, 2274 (“We think [the agency’s] old position is no more relevant than its current one—which is to say, not relevant at all.”). 89

Conclusion

Although the idea of an AKS statutory exception or a safe harbor is conceptually simple and attractive, in practice compliance attorneys and their clients need to be wary of over-reliance on them. In particular, attorneys need to pay attention to the law in their circuits concerning the employee safe harbor and should structure discount and GPO arrangements, if possible, to meet both the regulatory safe harbor and the statutory exception, rather than depend on arguments that the safe harbors impermissibly narrow the statutory exceptions. Such arguments should be reserved for defending arrangements and not for planning purposes. Counsel also need to be prepared to vigorously contest any suggestion by a criminal AUSA in an AKS case or by a civil AUSA or qui tam relator in a False Claims Act case that the various safe harbors contain an implied requirement of absence of wrongful intent. In this latter regard, the OIG could provide valuable assistance by clarifying that, if all of the specified requirements of a safe harbor are met, the parties to the arrangement are immune from prosecution under the AKS and not subject to administration sanction under the CMP Statute, regardless of intent.

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Endnotes

1 Section 1128B(b) of the Social Security Act, 42 U.S.C. § 1320a-7b(b). The AKS is a criminal statute, the violation of which is felony, punishable by imprisonment up to five years and a fine of up to $25,000. In addition, under the Civil Monetary Penalty (“CMP”) Statute, section 1128A of the Social Security Act, 42 U.S.C. § 1320a-7a, conduct that has been determined by the Secretary to violate the AKS is punishable by a CMP of $74,792. A conviction under the AKS or a finding of liability under the CMP Statute is also grounds for exclusion under section 1128(b)(7) of the Social Security Act, 42 U.S.C. § 1320a-7(b)(7).

2 The statutory exceptions appear at section 1128B(b)(3) of the Social Security Act, 42 U.S.C. § 1320a-7b(b)(3), and the regulatory exceptions (safe harbors) appear at 42 C.F.R. § 1001.952. There are currently 10 statutory exceptions and, depending on how one counts, between 25 and 28 regulatory safe harbors. As originally enacted in the Social Security Amendments of 1972, the AKS applied only to Medicare and Medicaid, violating the AKS was a misdemeanor, and the AKS contained no statutory exceptions. See §§ 242(b) and (c) of Pub. L. No. 92-603, 86 Stat. 1419, amending section 1877 of the Social Security Act and adding section 1909 of the same Act. In 1977, through the Medicare-Medicaid Anti-Fraud and Abuse Amendments, Pub. L. No. 95-142, § 4, 91 Stat. 1175, Congress added statutory exceptions for employment arrangements and discounts, and also upgraded violations to a felony. In section 14(a) of the Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93, 101 Stat. 680, 681-682, 689. Congress extended the AKS to state healthcare programs, moved the AKS to § 1128B of the Social Security Act, added the exception for Group Purchasing Organization (“GPO”) arrangements, and directed the Secretary to devise and publish regulatory safe harbors.
3 Section 1128(b)(3) of the Social Security Act, 42 U.S.C. § 1320a-7(b)(3); 42 C.F.R. § 1001.952 (title).

4 This article addresses some, but does not provide an in-depth analysis of any of the regulatory safe harbors that do not have a corresponding statutory exception and which have been issued by the OIG pursuant to its authority in section 1128(b)(3)(E) of the Social Security Act, 42 U.S.C. § 1320a-7(b)(3)(E). For an article postulating that the government has taken the position that intent is relevant when determining whether the prohibition (present in several regulatory safe harbors) on taking into account the volume or value of referrals, see Deaton, What is "Safe" About the Government's Recent Interpretation of the Anti-Kickback Statute Safe Harbors? . . . and Since When Was Stark an Intent-Based Statute?, 36 HOSPLW, No. 4, 549 (AHLA 2003).

5 See note 1, supra.


7 56 Fed. Reg. at 35954. See also 59 Fed. Reg. at 37203 (1994) ("[g]enerally speaking, however, the original [1991] final rule did describe payment practices that would be prohibited, where the unlawful intent exists, but for the safe harbor protection that has been granted.")

8 See, e.g., 68 Fed. Reg. 23149 ("Under the kickback statute, a number of statutory and regulatory "safe harbors" immunize certain arrangements that might otherwise violate the anti-kickback statute."); See also Fact Sheet "The Federal Anti-Kickback and Regulatory Safe Harbors" ("Safe harbors immunize certain payment and business practices that are implicated by the anti-kickback statute from criminal and civil prosecution [sic] under the statute") (November 1999), available at https://oig.hhs.gov/fraud/docs/safeharborregulations/safes.htm.


10 See 42 C.F.R. §§ 1001.952(a) – (bb).

11 Section 1128(b)(1) and (2), 42 U.S.C. § 1320a-7(b)(1) and (2), refer to remuneration as including that which is direct or indirect, and in cash or in kind.


14 Also, as discussed below, a few courts have held that intent to induce referrals renders the employment safe harbor inapplicable; however, those cases may be explained as holding that (in their view) the scope of the employment safe harbor, which protects remuneration by an employer to an employee for the "furnishing of any item or service for which payment may be made" by a federal healthcare program, does not extend to payment for increasing referrals. That is, some courts have held that the employment safe harbor itself provides that remuneration cannot be offered or paid for referrals.


16 106 F. Supp. 2d at 121 [emphasis added].


19 812. F. Supp. 2d at 48. Note that whereas Shaw and Westmoreland are from the same district, the opinions are by different judges.

20 812. F. Supp. 2d at 47.


22 The OIG takes the position, and several circuit courts have agreed, that the AKS is violated if only one purpose of the arrangement was to induce or pay for referrals of federal healthcare program business. See, e.g., United States v. Borus, 619 Fed. 377 (7th Cir. 2011); United States v. McClauchey, 217 F.3d 823 (10th Cir. 2000); United States v. Davis, 132 F.3d 1092 (5th Cir. 1998); United States v. Kats, 871 Fed. 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir. 1985).


27 The reasoning in the Advisory Opinion is somewhat suspect because Medicare did receive a discount, albeit Medicare Part A. In any event, the discount safe harbor was amended in 1999 to exclude from the definition of "discount" "[s]upplying one good or service without charge or at a reduced charge to induce the purchase of a different good or service without charge or at a reduced charge for the same good or service, unless the goods and services are reimbursed by the same Federal health care program on a fee-for-service or cost basis.", 52 Fed. Reg. at 112, quoting 1994 proposed rule, 59 Fed. Reg. at 37203.


29 See note 27, supra [emphasis added].

30 Courts have found that compliance with a safe harbor is an affirmative defense that must be pleaded and proved by the defendant. See, e.g., United States v. Williams, 218 F. Supp. 3d 730, 742 (N.D. Ill. Oct. 31, 2016) (collecting cases).

31 See 42 C.F.R. § 1001.952(i)(1)(ii)(B), (i)(ii)(B) ("[i]n establishing the terms of the agreement, neither party gives or receives remuneration in return for or to induce the provision or acceptance of business (other than business covered by the agreement) for which payment may be made in whole or in part by a Federal health care program on a fee-for-service or cost basis"); § 1001.952(u) (1)(ii)(E)(1)(same).

32 There is a statutory exception for managed care arrangements at section 1128(b)(3)(F) of the Act, 42 U.S.C. § 1320a-7(b)(3)(F), which is the statutory analog to the regulatory EMCO (eligible managed care organization) safe harbor at § 1001.952(e), but the statutory exception refers only to managed care organizations under section 1876 of the Act (if only because Congress did feel the need to update it to include Medicare Advantage and Medicaid managed care organizations). In addition to the EMCO safe harbor, there are also safe harbors for: Increased covered costs, reduced cost-sharing amounts, or reduced premium amounts offered by health plans (§ 1001.952(d)); Price reductions offered to health plans (§ 1001.952(m)); and Price reductions offered by contractors with substantial financial risk to managed care organizations (§ 1001.952(m)). There is considerable overlap among the safe harbors, and the EMCO safe harbor is by far the most useful.

33 See, e.g., AOs 98-18, 98-19, 99-4, 04-17, 08-10, 12-06, 13-15.

34 42 C.F.R. § 1001.952(d).


36 42 C.F.R. § 1001.952(i).


38 56 Fed. Reg. at 35981. Note that in response to a comment, the OIG said that for purposes of the safe harbor’s protection, part time as well as full time employees are included. 56 Fed. Reg. at 35981.

39 As discussed below, Chevron deference generally does not apply to an agency’s interpretation of a criminal statute.

40 Section 3121(d)(2) of 26 U.S.C. includes within the definition of “employee” “any individual who, under the usual common law rules applicable in determining the employer-employee relationship, has the status of an employee.”


42 503 U.S. at 333.


44 505 Fed. Appx. 385 (5th Cir. 2013).

45 505 Fed. Appx. At 388.

46 See also AO 07-03 (credit card rewards issued to professional and administrative/clerical staff were for the furnishing of items or services payable under federal healthcare program and were protected by the employee safe harbor); AO 12-06 (payments to anesthesia personnel for administrative and logistical support could be protected by the safe harbor); AO 12-08 (physician employee’s interpretation of sleep studies and related administrative tasks were protected by statutory exception and regulatory safe harbor).


49 56 Fed. Reg. at 35981.

50 December 22, 1992 Letter from D. Mccarry Thornton to TJ. Sullivan, available at https://oig.hhs.gov/fraud/docs/safeharborregulations/acquisition122292.htm. This statement appears inconsistent with other OIG pronouncements concerning the breadth of protection afforded by the safe harbor, but it is hard to attach much importance to it because of its hedging. Why does it say that payments continued on page 14
for referrals would “likely not” be covered by the safe harbor? Either they are covered or not. In Hericks v. Lincare Inc., 2014 U.S. Dist. LEXIS 39706, *5*-54 (E.D. Pa. 2014), the court was not impressed with the letter, noting that it was over 20 years old and that the letter stated only that payments for referrals were only “likely” not covered by the safe harbor.

51 157 F.3d 833 (11th Cir. 1998).

52 157 F.3d at 839.


54 The Luis court incorrectly quotes the safe harbor as saying that the payment to the employee must be for the furnishing of any item or service for which payments may be made in whole or in part under Medicare. The safe harbor includes the language “Medicare, Medicaid or other Federal health care programs.”

55 619 F.3d 774, 782 (7th Cir. 2011).


57 2013 U.S. Dist. Lexis 167882, at *23 [emphasis in the original].


59 2016 U.S. Dist. LEXIS 80160, at *75-76 [emphasis in the original].

60 2016 U.S. Dist. LEXIS 80160, at *78. The court’s statement, that if the safe harbor was unavailable, the marketing activities would be illegal, is a bit hyperbolic. The OIG seems to have backed off its initial position that percentage service for which payments may be made for independent sales agents are at least a “technical violation” of the AKS. Compare 56 Fed. Reg. at 35974 ("many marketing and advertising activities may involve at least technical violations of the statute") with AO 99-3 ("any comparison arrangement between the Seller 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, irrespective of the methodology used to compensate the agent").

61 2016 U.S. Dist. LEXIS 80160, at *79.


65 2015 U.S. Dist. LEXIS 77773 at 17, *23*.


67 64 Fed. Reg. at 63527-28. Although the OIG has taken the position that the safe harbors supersede the statutory exception, the following statement is inconsistent with that position: “Such arrangements result in the programs being overcharged and are not protected by either the statutory exception or regulatory safe harbor for discounts.” 64 Fed. Reg. at 63526.


The bill would specifically exclude the practice of discounting or other reductions in price from the range of financial transactions to be considered illegal under medicare and medicaid, but only if such discounts are properly disclosed and reflected in the costs for which reimbursement could be claimed. The committee included this provision to ensure that the practice of discounting in the normal course of business transactions would not be deemed illegal. In fact, the committee would encourage providers to seek discounts as a good business practice which results in savings to medicare and medicaid program costs.


69 The regulatory safe harbor exceptions from the definition of “discount” “[s]upplying one good or service without charge or at a reduced charge to induce the purchase of a different good or service, unless the goods and services are reimbursed by the same Federal health care program using the same methodology and the reduced charge is fully disclosed to the Federal health care program and accurately reflected where appropriate, and as appropriate, to the reimbursement methodology.” 42 C.F.R. § 1001.952(h)(5)(ii). The OIG has not provided clear guidance on what it means by the “same methodology.” In the November 19, 1999 clarification to the regulatory safe harbor on discounts, the OIG seemed to indicate that items paid under the same reimbursement methodology, such as the hospital DRG payment system are “reimbursed . . . using the same methodology.” 64 Fed. Reg. at 63540. However, in 2000, the OIG issued a proposed rule that, among other things, contained a proposal to “clarify” what constitutes the same payment methodology, and the proposed rule may be read as suggesting that same payment methodology means same payment, i.e., the discounted items could not be each separately reimbursable but would have to be part of a bundled payment, e.g., “the same DRG, prospective payment or per diem payment, but . . . not . . . fee schedules.” 65 Fed. Reg. 63036 (October 20, 2000). At any rate, two years later, the OIG withdrew the proposed rule from its list of active rules under consideration, see 67 Fed. Reg. 11930 (March 18, 2002), and it has not been heard from since. In a 1994 Special Fraud Alert (“SFA”), available at https://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html, the OIG stated that “[t]he statutory exception and ‘safe harbor’ for ‘discounts’ does [sic] not apply to immunize parties to this type of transaction, since discounts on the composite rate tests are offered to induce referral of other tests. See 42 C.F.R. 1001.952(h)(3)(ii).” In fact, as implied by the OIG’s citation to the regulations only, the statutory exception contains no such limitation.

70 Section 1128B(b)(3)(C) of the Social Security Act, 42 U.S.C. § 1320a-7(b)(3)(C).

71 Cheviron U.S.A., Inc. v. NRDC, Inc., 467 U.S. 837 (1984). Cheviron is arguably the most important case in the area of administrative law, and sets forth a two-step analytic framework for judicial review of challenged agency regulations. At step 1, if the court finds that Congress has directly spoken to the issue, that is the end of the matter, and the agency regulation is either upheld or struck down depending on whether the regulation comports with the court’s view of the plain reading of the statute. If, however, the statute is ambiguous on the matter at issue, the reviewing court proceeds to step 2. At step 2, if the regulation is a permissible (i.e., reasonable) reading of the ambiguous statute, it must be upheld (i.e., it is given “Cheviron deference”), regardless of whether it is the best reading. 467 U.S. at 842-43.

72 810 F.3d 1019, 1027 (6th Cir. 2016) (parallel citation omitted).


74 56 Fed. Reg. at 35957.

75 There is no legislative history, in either the original statute or in Pub. L. 100-93, indicating that the Secretary has the authority to narrow the safe harbors.

76 The legislative history of section 14(a) of Pub. L. 100-93 is silent on the issue.

77 64 Fed. Reg. at 63527.

78 Section 1102(a) of the Social Security Act, 42 U.S.C. § 1302(a).

79 Note that the statutory exception for remuneration paid by a vendor to a GPO provides that the GPO must disclose to a provider of services “in such form and manner as the Secretary requires” the amount received from each vendor with respect to purchases made by or on behalf of the provider of services. Section 1128B(b)(3)(C) of the Social Security Act, 42 U.S.C. § 1320a-7(b)(3)(C). The quoted language both reinforces that the Secretary has some role to play with respect to the statutory exceptions, as well as indicates that the role is limited to what Congress prescribed. Note that in the physician self-referral statute (the Stark law), when Congress wished to give the Secretary authority to add additional requirements to an exception it said so. See 42 U.S.C. §§ 1395nn(e)(1)(A) (vi), (e)(1)(B)(vi), (e)(2)(D), (e)(3)(A)(vii), (e)(5)(C), (e)(6)(B), (e)(7)(A)(vii).

80 See note 15, supra.

81 See 106 F.Supp. 2d at 118-119. Although the court states that the statutory exception and regulatory safe harbor are independent from each other “For the reasons stated previously (see Part V.C above),” there are in fact no reasons given for the court’s conclusion.
This would seem to be true irrespective of whether the OIG’s interpretation is being applied by the DOJ in a criminal case or by the OIG in an action brought under the CMP Statute. Although the CMP Statute is a civil statute, the violation under the CMP Statute that is relevant for present purposes “commits an act described in paragraph (1) or (2) of section 1128B(b).” Section 1128A(a)(7), 42 U.S.C. § 1320a-7a(a)(7). Thus, because it is necessary to engage in conduct that violates the AKS in order to be sanctioned under section 1128A(a) (7), an OIG interpretation in a CMP Statute case that seeks to punish illegal kickbacks is necessarily an OIG interpretation of the AKS.

See Crandon v. United States, 494 U.S. 152, 177-178 (1990) (“Besides being unentitled to what might be called ex officio deference under Chevron, this expansive administrative interpretation of § 209(a) is not even deserving of any persuasive effect. Any responsible lawyer advising on whether particular conduct violates a criminal statute will obviously err in the direction of inclusion rather than exclusion — assuming, to be on the safe side, that the statute may cover more than is entirely apparent. That tendency is reinforced when the advice-giver is the Justice Department, which knows that if it takes an erroneously narrow view of what it can prosecute the error will likely never be corrected, whereas an erroneously broad view will be corrected by the courts when prosecutions are brought. Thus, to give persuasive effect to the government’s expansive advice-giving interpretation of § 209(a) would turn the normal construction of criminal statutes upside-down, replacing the doctrine of lenity with a doctrine of severity.”). A more succinct statement comes from Abramski v. United States, —— U.S. ——, 134 S.Ct. 2259, 2274 (“We think [the agency’s] old position is no more relevant than its current one—which is to say, not relevant at all.”)


COMMMUNITY BENEFIT, ACCOUNTABLE CARE ORGANIZATIONS AND POPULATION HEALTH: TAX IMPLICATIONS FOR ACOS AND NONPROFIT HOSPITAL PARTICIPANTS

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Introduction

Accountable Care Organizations ("ACOs") were initially designed for groups of physicians, hospitals and other healthcare providers to deliver coordinated high-quality care to Medicare patients via the Medicare Shared Savings Program ("MSSP"). The MSSP was established by the Patient Protection and Affordable Care Act ("PPACA") to improve quality of care for Medicare beneficiaries and reduce unnecessary costs. PPACA included provisions to use Medicare to broadly implement ACO models to change incentives for how medical care is delivered and paid for by moving away from a system rewarding quantity of services to one rewarding the improvement of health outcomes.

Since their inception in 2010, ACOs have expanded in scope to include Medicaid and private commercial insurance arrangements. ACOs can be established as organizations separate from their participant owners or structured as joint venture pass-through entities, i.e., partnerships and limited liability companies ("LLCs"). Tax implications and requirements differ for tax-exempt participants depending upon organizational structure and ACO activities. Ideally, ACOs seek to attain tax-exempt status consistent with Internal Revenue Service ("IRS") Notice 2011-20 as further described in IRS Fact Sheet 2011-11.

The question of whether an ACO can qualify for tax-exempt status was addressed in IRS Private Letter Ruling ("PLR") 201615022. To date this is the only PLR issued on the subject of ACOs qualifying as tax-exempt organizations. Based upon information provided, the IRS issued an adverse determination in consideration of an ACO’s application for recognition of exemption from federal income tax under section 501(a) of the Internal Revenue Code ("IRC"). The ACO was created by a nonprofit health system and included independent private physicians by agreement. The IRS determined that the ACO did not qualify for exemption under section 501(c)(3) of the IRC. PLRs may not be used or cited as precedent by entities other than the recipient, they provide insight into the IRS’s position and interpretation of tax law as applied to a specific set of facts.

PLR 201615022 raises concerns among nonprofit hospitals and other healthcare organizations seeking to establish ACOs with private physician groups engaged in the MSSP as well as non-MSSP arrangements with commercial payers. The IRS concluded that the ACO failed to establish that it was organized and operated for exempt purposes, as negotiation of payer agreements on behalf of its non-healthcare system affiliated physicians only indirectly benefitted the community. The private benefit to those members was not found to be quantitatively or qualitatively incidental or insubstantial in comparison to the community benefit produced by the ACO’s activities.

This article will examine the application of the community benefit standard to ACOs under section 501(c)(3) of the IRC. Namely, what are the general requirements for tax-exempt status? What are the tax-exempt requirements for ACOs? What are the tax implications for ACOs participating in non-MSSP activities in light of PLR 201615022? What are the tax considerations for ACOs and their participant members choosing to organize as pass-through entities?

What are the Requirements for Tax Exempt Status?

Section 501(c)(3) provides for the exemption from federal income tax of corporations organized and operated exclusively for charitable, scientific or educational purposes if no part of the organization’s earnings inures to the benefit of any private shareholder or individual. Treasury Regulation ("Treas. Reg.") 1.501(c)(3)-1(c)(1) provides that an organization will be regarded as operated exclusively for one or more exempt purposes only if it engages primarily in activities that accomplish one or more exempt purposes specified in section 501(c)(3). Treas. Reg. 1.501(c)(3)-1(d)(1)(ii) provides that an organization is not organized or operated exclusively for exempt purposes unless it serves a public rather than a private interest. It further states that "to meet the requirement for this subdivision it is necessary for an organization to establish that it is not organized and operated for the benefits of private interests." Treas. Reg. 1.501(c)(3)-1(d)(2) provides that the term “charitable” is used in section 501(c)(3) in its generally accepted legal sense. To qualify for exemption from federal income tax under section 501(c)(3), a nonprofit entity must be organized and operated exclusively in furtherance of some purpose considered charitable in the generally accepted legal sense of that term, and the entity may not be operated directly or indirectly for the benefit of private interests.
In the general law of charity, the promotion of health is considered a charitable purpose. A nonprofit organization whose purpose and activity are providing hospital care is promoting health and may qualify as organized and operated in furtherance of a charitable purpose.

Prior to 1969, the IRS applied a financial ability standard as a requirement for a hospital to qualify for section 501(c)(3) status. The IRS in Rev. Rul. 56-185 set forth the requirements that a hospital must be organized as a nonprofit charitable organization for the purpose of operating a hospital for the care of the sick or injured. It must be operated to the extent of its financial ability for those not able to pay for the services and not exclusively for those who are able and expected to pay, i.e., the charity care standard. It must not refuse to accept patients in need of care who cannot pay for such services.

In 1969 the IRS, in Rev. Rul. 69-545, replaced the financial ability standard with the community benefit standard. In evaluating whether a nonprofit hospital qualifies as an organization described in section 501(c)(3), Rev. Rul. 69-545 compares two hospitals. Hospital A is controlled by a board of trustees composed of independent civic leaders. The hospital maintains an open medical staff with privileges available to all licensed physicians. It operates a full-time emergency department open to all patients able to pay themselves or regardless of ability to pay. It admits all patients able to pay themselves or through third party payers.

Hospital B is controlled by physicians who have a substantial economic interest in the hospital. The hospital restricts the number of physicians admitted to the medical staff, enters into favorable rental agreements with the individuals who control the hospital and limits emergency room and hospital admissions substantially to the patients of physicians who control the board.

In considering whether a nonprofit hospital is operated to serve a private benefit, the IRS weighs all of the relevant facts and circumstances in each case, including the use and control of the hospital. The fact that a hospital operates at an annual surplus of receipts over disbursements does not preclude its exemption. By using its surplus funds to improve the quality of patient care, expand its facilities and advance medical training, education and research programs, the hospital is operating in furtherance of its exempt purpose.

Taking into the account the factors listed above, the IRS concluded that Hospital A qualified for exemption as a 501(c)(3) organization. In contrast, Hospital B continued to operate for the private benefit of its original owners, rather than for the exclusive benefit of the public. Therefore, Hospital B did not qualify for exemption from federal income tax under section 501(c)(3).

Organizational Test, Operational Test and Inurement

In sum, to qualify for exemption from federal income tax under section 501(c)(3) an organization must pass both an organizational and operational test under Treas. Reg. 1.503(c)(3)-1. The organizational test relates to the language of the organization’s governing documents. This language must limit the purposes of the organization to one or more exempt purposes described in section 501(c)(3) and must not expressly empower the organization to engage (except to an insubstantial degree) in any activities that do not further one or more exempt purposes per Treas. Reg. 1.501(c)(3)-1(b)(1)(i).

The operational test requires the organization to engage primarily in activities that accomplish one or more exempt purposes under section 501(c)(3). Treas. Reg. 1.501(c)(3)-1(c)(1) states that the test is not met if more than an insubstantial part of the activities is not in furtherance of an exempt purpose. By focusing upon primary activities and suggesting that an insubstantial part of those activities may further a non-exempt purpose, the Treas. Reg. confirms that operated exclusively means operated primarily for exempt purposes.

Section 501(c)(3) organizations are further prohibited from engaging in activities that result in inurement of the organization’s net earnings to insiders. Treas. Reg. 1.503(c)(3)-1(c)(2) explains the prohibition against inurement: an organization is not operated exclusively for one or more exempt purposes if its net earnings inure in whole or in part to the benefit of private individuals. Treas. Reg. 1.501(a)-1(c) states that the words private shareholder or individual in section 501 refer to persons having personal and private interest in the activities of the organization.

Inurement occurs when a person who is in a position to influence the decisions of the organization receives disproportionate benefits, such as excessive compensation or rent, a below market rate loan, or improper economic gain from sales or exchanges of property with the exempt organization.

Community Benefit

Per Rev. Rul. 69-545, hospitals can qualify as tax-exempt organizations as long as they offer a community benefit. The IRS definition of community benefit is found in the instructions for Schedule H, which accompanies the Form 990 filed annually by nonprofit organizations. It includes financial assistance, government sponsored means tested programs (unpaid costs of public programs), community health improvement services, health professions education, subsidized health services, research, cash-in-kind contributions, community building activities, and community benefit operations.

Hospitals use Schedule H to provide information on the activities and policies of community benefit provided by its hospital facilities and other

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non-hospital healthcare facilities operated during the previous calendar year. This includes facilities operated either directly or through disregarded entities or joint ventures.21

Form 990, Schedule H, Part V, section B was revised for tax years beginning in 2010 and 2011 to include additional questions relating to new section 501(r) reporting requirements.22 IRS Bulletin 2015-15, TD 9708 points out that commenters in response to the April 5, 2013 proposed Community Health Needs Assessment (“CHNA”) requirement regulations under section 501(r)(3) asked that separate entities cooperating in ACOs or similar integrated care models be treated as a single “hospital organization” for purposes of section 501(r), arguing that this would create administrative efficiencies as the participating organizations develop one standard set of policies and procedures and would result in less confusion for patients as they move through a “continuum of care.”

The final regulations did not adopt this suggestion, but the Treasury Department and the IRS noted in the commentary to the regulation that multiple hospital facilities may have identical financial assistance policies (“FAPs”) and other policies established for them or share one joint policy document so long as the information in the policy or policies is accurate for all such facilities and any joint policy clearly states that it is applicable to each facility.23 Separate hospital facilities that define their community to be the same may conduct a joint CHNA and adopt a joint implementation strategy addressing the significant health needs identified in the joint CHNA. Thus, the final regulations provide opportunities for separate hospital facilities participating in an ACO to jointly comply with many of the section 501(r) requirements.24

What are the Tax-Exempt Requirements for ACOs?

IRS Notice 2011-20

In Notice 2011-20 the IRS considered the application of IRC provisions governing tax-exempt organizations participating in the MSSP. The IRS anticipated that tax-exempt organizations typically will be participating in the MSSP through an ACO along with private parties. The IRS further anticipated that a tax-exempt organization’s participation might take any of a variety of forms, including membership in a nonprofit membership corporation, ownership of shares in a corporation, ownership of a partnership interest in a partnership (or a membership interest in an LLC) or contractual arrangements with the ACO or its other participants, or both.

To avoid adverse tax consequences, the tax-exempt organization must ensure that its participation in the MSSP through an ACO is structured so that its net earnings do not inure to the benefit of insiders and that it is not operated for the benefit of private parties participating in the ACO. The IRS indicated that a tax-exempt organization’s participation in the MSSP through an ACO will not result in inurement or impermissible private benefit to the ACO private party participants if specific requirements are met.25

The IRS noted that it understands that some tax-exempt organizations may participate in ACOs that conduct activities unrelated to the MSSP (“non-MSSP activities”), including entering into and operating under shared savings arrangements with other types of health insurance payers. But many non-MSSP activities conducted by or through an ACO are unlikely to lessen the burdens of government within the meaning of Treas. Reg. 1.501(c)(3)-1(d)(2). Negotiating with private health insurers on behalf of unrelated parties generally is not a charitable activity, regardless of whether the negotiated agreement involves a program aimed at achieving cost savings in healthcare delivery. However, the IRS recognizes that certain non-MSSP activities may further or be substantially related to an exempt purpose. For example, ACOs may participate in shared-savings arrangements with Medicaid, which may further the charitable purpose of relieving the poor, distressed and underprivileged.26

IRS Fact Sheet ("FS") 2011-11

IRS Fact Sheet (“FS”) 2011-11 confirmed the IRS expectations set forth in Notice 2011-20 regarding the MSSP and ACOs. It also provides additional information for charitable organizations participating in the MSSP as well as an ACO’s non-MSSP activities. Whether an ACO’s conduct of non-MSSP activities will jeopardize the status of a tax-exempt participant is analyzed under the general rules applicable to charitable organizations and depends on all of the facts and circumstances, according to IRS FS 2011-11. These include whether the non-MSSP activities further an exempt purpose described in section 501(c)(3), i.e., a charitable purpose; are attributable to the tax-exempt participant; represent an insubstantial part of the participant’s total activities;27 or do not result in inurement of the tax-exempt participant’s net earnings to a private interest or in an impermissible private benefit.28

If the ACO’s activities are attributable to a tax-exempt participant (because the ACO is treated as a partnership for tax purposes), the participant’s tax-exempt status will not be jeopardized if the ACO’s non-charitable activities represent no more than an insubstantial part of the participant’s total activities. However, the presence of a single non-exempt
purpose, if substantial in nature, may jeopardize a participant’s tax-exempt status.32

Furthermore, an ACO engaged in both MSSP and non-MSSP activities can qualify for section 501(c)(3) tax exemption. The IRS stated that it recognizes that certain non-MSSP activities conducted by an ACO may further a charitable purpose. If an ACO engages exclusively in MSSP and non-MSSP activities that accomplish charitable purposes, it may qualify for tax-exemption under section 501(c)(3), as long as the ACO meets all of the other requirements for tax exemption under that section.33

Relevance of IRS Notice 2011-20 and FS 2011-11 to Non-MSSP Activities

The IRS in Notice 2011-20 summarized how the IRS expected existing IRS guidance might apply to section 501(c)(3) organizations, such as charitable hospitals participating in the MSSP through ACOs. It also solicited comments on whether existing guidance relating to the IRC provisions governing tax-exempt organizations is sufficient for those tax-exempt organizations planning to participate in the MSSP through ACOs and if not, what additional guidance was needed. The IRS further solicited comments concerning whether guidance is needed regarding the tax implications for tax-exempt organizations participating in activities unrelated to the MSSP, including shared savings arrangements with commercial health insurance payers through ACOs.34

Specifically, the IRS requested comments regarding how a tax-exempt organization’s participation in particular non-MSSP activities through an ACO further or are substantially related to an exempt purpose. The IRS noted that comments should describe the activities a tax-exempt organization might expect to participate in through an ACO and address under what rationale participation in such non-MSSP activities might further exempt purposes and also what criteria, requirements and safeguards would ensure the furtherance of those exempt purposes.

Comments were to take into account two principles of existing law. First, although the promotion of health has been recognized as a charitable purpose, not every activity that promotes health supports tax exemption under section 501(c)(3). Second, if a tax-exempt organization is a partner (or member, in the case of an LLC) of an ACO treated as a partnership for federal tax purposes, the ACO’s activities will be attributed to the tax-exempt organization for the purposes of determining both whether the organization operates exclusively for exempt purposes and whether it is engaged in an unrelated trade of business.35

IRS FS 2011-11, following completion of the Notice 2011-20 comment period, set forth the IRS’s guidance relative to the MSSP and ACOs, participation by charitable organizations in an ACO, MSSP activities and non-MSSP activities, and tax status of ACOs. In it, the IRS recognized that there are circumstances in which an ACO’s non-MSSP activities can further a charitable purpose while noting that not every activity promoting health supports tax exemption under section 501(c)(3). The IRS addressed the fact that ACO non-MSSP activities not furthering a charitable purpose would not necessarily place its tax-exempt participants in jeopardy, but the answer will depend on the relevant facts and circumstances.

The IRS also addressed whether an ACO’s non-MSSP activities always generate unrelated business income ("UBI") for its tax-exempt participants, i.e., as certain non-MSSP activities may be substantially related to the exercise or performance of a charitable purpose, noting that whether an ACO’s activities not substantially related to a charitable purpose will generate UBI will depend on a variety of factors.

And finally, the IRS acknowledged that an ACO engaged in both MSSP and non-MSSP activities can qualify for tax exemption, provided it engages in activities that accomplish one or more charitable purposes. Thus, while the primary purpose of both IRS Notice 2011-20 and FS 2011-11 was to provide guidance for MSSP activities, implications and considerations for non-MSSP activities were included.36

What are the Tax Implications for ACOs Participating in Non-MSSP Activities In Light of PLR 201615022?

Negotiating with Private Insurers on Behalf of Unrelated Parties Generally Not a Charitable Activity

The requestor in PLR 201615022, an ACO not participating in the MSSP, was incorporated as a nonprofit corporation for charitable, scientific or educational purposes within the meaning of section 501(c)(3), specifically to promote and support, directly or indirectly, the interests and purposes of a nonprofit healthcare corporation recognized as tax-exempt under section 501(c)(3) and classified as a public charity under section 509(a)(1).

The ACO was formed by a health system, itself a nonprofit healthcare corporation recognized as tax-exempt under section 501(c)(3) and classified as a public charity under section 509(a)(1). The health system established the ACO to serve as the legal and operational vehicle to achieve clinical integration, coordination, and accountability among participating physicians.

The ACO formed a clinically integrated network of healthcare providers to advance the goals of the Triple Aim, i.e., improving the individual experience of care (including quality and satisfaction), improving the health

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of populations and reducing the per capita costs of care.37 Network participants included physicians employed by the health system as well as those from independent practice groups who were members of the system’s medical staff and those practicing at other non-system hospitals.

The ACO developed and implemented performance measures to assess the care delivery of participating physicians. Financial incentives were established to motivate physicians to achieve improvements, tying payments to their collective success in achieving Triple Aim goals.

The ACO established infrastructure for collecting, aggregating and analyzing data, including an electronically integrated clinical information data warehouse, a patient satisfaction survey tool, and clinical infrastructure necessary for tracking provider performance and sharing clinical data.

The ACO acted as the representative of all participating physicians, including the independent and non-system affiliated physicians in the negotiation and execution of agreements with third-party payers. Those agreements linked rewards and penalties for participants to their achievement of ACO performance measures.

The IRS in PLR 201615022 noted that one of the ACO’s substantial activities was the negotiation of payer agreements on behalf of its healthcare physician participants, half of whom were not employed by the health system or system hospitals. Those activities were deemed primarily beneficial to the non-system affiliated physicians and other healthcare provider participants because the ACO was providing them with specific long- and short-term planning information that could be used in their business activities.38 Therefore, the ACO was not engaged primarily in activities supporting a charitable purpose.

As noted above, to be exempt as an organization described in section 501(c)(3), an organization must be both organized and operated exclusively for one or more exempt purposes.39 An organization is not organized or operated exclusively for an exempt purpose unless it serves a public rather than a private interest. Thus, to meet the public purpose requirements it is necessary for an organization to establish that it is not organized or operated for the benefit of private interests such as designated individuals, the creator or his family, shareholders of the organization, or persons controlled, directly or indirectly by such private interests.40

On that point the IRS in PLR 201615022 concluded that the ACO’s negotiation of payer agreements on behalf of the non-system affiliated physicians only indirectly benefited the community as a whole. The private benefit to those members was not considered qualitatively or quantitatively incidental or insubstantial in comparison to the community benefit produced by the ACO’s activities. Rather, the negotiation of payer agreements on behalf of independent healthcare providers and those employed at other hospitals and healthcare systems constituted a substantial part of the ACO’s activities and conferred an impermissible private benefit on participants not affiliated with the system.41

However, the operational test of Treas. Reg. 1.501(c)(3)-1(c)(1) focuses on the organization’s primary activities and suggests that an insubstantial part of those activities may further a non-exempt purpose.42 Since that operated “exclusively” means operated “primarily” for exempt purposes, so long as the ACO’s activities are in furtherance of a charitable purpose, i.e., providing a community benefit per Rev. Rul. 69-545, the operational test can be met.

Here, the IRS denied the request for tax-exempt status, as the ACO provided negotiation benefit to non-system provider participants and failed to demonstrate sufficient community benefit to offset those negotiations. While the ACO contended that all of its time and resources were dedicated to the furtherance of Triple Aim health reform goals, it provided little supporting evidence of what those efforts entailed. It did develop and implement performance measures and established data infrastructure for collecting, aggregating and analyzing data. But those activities were essential in assessing participating physician performance relative to financial incentives. The ACO did not articulate specific programs, processes or best practices employed to improve the health of the communities served, i.e., community benefit.

Would Increased Community Benefit Have Persuaded the IRS to Approve the ACO’s Application for Exempt Status?

Notwithstanding the IRS’s conclusion that private insurer cost savings do not provide a public benefit, cost reduction represents only one Triple Aim goal. The remaining two goals, improving patient access to and quality of care and improving population health, clearly reflect charitable purposes within the context of community benefit. Community health improvement services and programs designed in response to a community’s CHNA-identified health priorities certainly enhance population health. And while ACOs organized as tax-exempt corporate entities do not complete Schedule H with their annual Form 990 filings, they must still demonstrate that they meet the requirements of charitable organizations. Moreover, engaging in activities that support and improve population
health arguably serves a public interest under the operational test of Treas. Reg. 1.501(c)(3)-(d)(1)(ii).

While the ACO that requested the PLR was unsuccessful in persuading the IRS to approve its application for tax-exempt status, arguably an alternative, yet untested, community health improvement approach to providing community benefit might succeed.

ACOs can provide a number of community health improvement services, such as:

- Community health education outreach, including classes or lectures on disease conditions, support groups that go beyond the current standard of care and self-help programs for persons and families facing health problems.
- Community-based clinical services where there is no patient bill, including screenings and one-time occasionally held clinics.
- Healthcare support services, such as transportation to improve access for low-income persons to healthcare in the community and not for the purpose of increasing referrals to the organization or its affiliated physicians.
- Social and environmental improvement activities, such as removing materials such as asbestos and lead that harm residents in public housing and working to improve availability of fresh fruits and vegetables in areas known as “food deserts.”

IRS regulations acknowledge that health needs identified in a CHNA may include ensuring adequate nutrition or addressing social, behavioral and environmental factors that influence health in the community. While tax-exempt hospitals commonly engage in health improvement interventions as part of their community benefit activities, ACOs are likewise designed to be accountable for improving their patients’ health as well as of that of the entire community. They can do so by collaborating with local nonprofits and governmental agencies to address social determinants of health, e.g. housing, poverty and unsafe neighborhoods, consistent with Treas. Reg. 1.501(r)-3(b)(4).

The breadth of ACO community health improvement efforts was recently assessed by the Premier Research Institute. The Institute, with support from the Robert Wood Johnson Foundation, conducted survey and interview research of 19 ACOs from September 2015 to April 2016. ACOs included in this survey included one or more (1) owned by a single hospital or health system, (2) owned by multiple hospitals, (3) affiliated with a hospital or health system, (4) organized as a partnership of hospitals, or (5) operated as a division of a health system. Fifteen ACOs were exclusively MSSP ACOs, two were Medicare Pioneer ACOs, one ACO serviced Medicare with Centers for Medicare & Medicaid Services (“CMS”) Medicare Advantage Programs and Medicaid business, and one was a MSSP ACO that also had commercial and Medicare contracts.

Of the 19 ACOs, eight reported they had completed an ACO-CHNA; five responded that the hospital or health system was required to and had completed a CHNA; three weren’t aware whether a CHNA was completed; one reported that a CHNA was conducted by the health department; and two reported that no CHNA had been completed.

ACO programs and services offered to improve health included patient navigators or community health workers or social workers, chronic disease management clinics or programs, health education, nutrition or other weight management services, smoking cessation clinics, health fairs and screenings and weight, wellness or exercise programs.

From both a population health and community benefit perspective, it is widely accepted that tax-exempt hospitals should devote more resources to community health improvement activities. ACOs, especially those which tax-exempt hospitals are participants, can also serve this vital community health improvement role, providing community benefit to the populations and communities served, thereby furthering a charitable purpose as nonprofit corporate entities or as joint ventures, as addressed below. ACOs and their provider participants are ideally suited to focus upon population health efforts and community partnerships and interventions, as are their tax-exempt hospital participants.

As noted in IRS Service Bulletin 2015-1, the final regulations, Treas. Reg. 1.501-3, provide opportunities for separate hospital facilities participating in an ACO to jointly comply with many section 501(r) requirements. Hospitals within the same community conducting a joint CHNA can adopt a joint Community Health Improvement Plan (“CHIP”) implementation strategy addressing significant health needs. Strategies can include community health improvement services, community building activities and community benefit operations. An ACO, with one or more tax-exempt hospitals as a participant, is likewise poised to engage in community health improvement services for identified health needs prioritized in the hospitals’ joint CHNA. ACOs, by definition, represent the ambulatory platform upon which community benefit and population health initiatives operate.

So, if ACOs commit greater effort and resources to community health improvement services, they stand a better chance of obtaining tax-exempt status. Even ACOs that forego tax-exempt status, choosing instead to organize as pass-through entities, should devote sufficient attention to community health improvement services in support of their nonprofit hospital participants and communities served.

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What are the Considerations for ACOs Choosing to Organize as Pass-Through Entities?

An ACO organized as a pass-through entity, e.g., a partnership or LLC, cannot qualify for tax-exempt status under section 501(a)(1) as an organization described under section 501(c)(3). However, if carefully structured, i.e., consistent with Revenue Ruling (“Rev. Rul.”) 98-15 and Rev. Rul. 2004-51 guidance, the ACO’s nonprofit hospital members can retain their tax-exempt status and avoid UBI tax exposure for ACO activities.

Rev. Rul. 98-15

Rev. Rul. 98-15 examined the tax consequences described in section 501(c)(3) in joint ventures with for-profit entities. Rev. Rul. 98-15 compared two situations where an exempt hospital formed an LLC with a for-profit corporation and contributed its hospital and all of its operating assets to the LLC, which then operated the hospital.

In the first situation, the exempt organization continued to further charitable purposes when it participated in the joint venture. Favorable factors included the commitment of the joint venture to give charitable purposes priority over maximizing profits in the operation of the hospital, the community makeup and structure of the board, the voting control held by the exempt organization’s representatives on the board, the specifically enumerated powers of the board, and the reasonable terms and conditions of its management contract.

In contrast, in the second situation the organization failed the operational test when it participated in the joint venture because the joint venture activities resulted in greater than incidental private benefit. The LLC violated the section 501(c)(3) requirements of an exempt organization because it would not be operated exclusively for exempt purposes. The LLC was not engaging primarily in activities that furthered an exempt purpose. There was no binding obligation in the LLC’s governing documents for it to further charitable purposes or otherwise provide its services to the community as a whole.

Rev. Rul. 2004-51

Rev. Rul. 2004-51 involved an ancillary joint venture that addressed two issues. The first was whether an organization continued to qualify for exemption from federal income tax as an organization described in section 501(c)(3) when it contributed a portion of its assets to, and conducted a portion of its activities through, an LLC formed with a for-profit corporation. The second was whether the organization was subject to UBI tax under section 511 on its distributive share of the LLC’s income.

This revenue ruling involved a tax-exempt university that formed a domestic LLC with a for-profit company that specialized in conducting interactive video programs. The sole purpose of the LLC was to offer teacher training seminars at off-campus locations using interactive video technology. The facts established that the university’s activities conducted through the LLC constituted a trade or business that was substantially related to the exercise and performance of the university’s exempt purposes and functions. Although the for-profit company arranged and conducted all aspects of the teacher training seminars, the university alone approved the curriculum, training materials and instructors and determined the standards for successfully completing the seminars.

All contracts entered into by the LLC were at arm’s length and for fair market value. The university’s and for-profit organization’s ownership interests in the LLC were proportional to their respective capital contributions. All returns of capital, allocations and distributions by the LLC were proportional to the university’s and for-profit organization’s ownership interests. The fact that the for-profit organization selected the locations and approved the other personnel necessary to conduct the seminars did not affect whether the seminars were substantially related to the university’s educational purpose. The teacher training seminars the LLC conducted using interactive video technology covered the same content as the seminars the university conducted on its own campus. The LLC’s activities expanded the reach of the university’s teacher training seminars to individuals who otherwise could not be accommodated at the university’s campus.

The manner in which the LLC conducted the teacher training seminars contributed importantly to the accomplishment of the university’s educational purposes. The activities of the LLC were substantially related to the university’s educational purposes pursuant to Treas. Reg. 1.513-1(d)(2). The IRS ruled that the university was not subject to UBI tax under section 511 on its distributive share of the LLC’s income.

Application to ACOs

To date the only IRS guidance specific to ACOs is provided in IRS Notice 2011-20, IRS FS 2011-11, and PLR 201615022. IRS Notice 2011-20 and IRS FS 2011-11 direct ACOs treated as partnerships and their tax-exempt participants to consult IRS guidance regarding joint ventures, e.g., Rev. Rul. 98-15 and Rev. Rul. 2004-51 for examples of partnerships conducting activities that further a charitable purpose of a tax-exempt participant. The IRS’s only reference in PLR 201615022 to Rev. Rul. 98-15 is in the context of...
Thus, while the use of a non-profit organization as a partner in a for-profit activity is often considered advantageous, the application of IRS Notice 2011-20 and IRS FS 2011-11 is untested, it is certainly a viable argument.

Applying these two rulings to ACOs, if a tax-exempt organization is a partner (or member, in the case of an LLC) of an ACO treated as a partnership for federal tax purposes, the ACO’s activities will be attributed to the tax-exempt organization for purposes of determining both whether the organization operates exclusively for exempt purposes and whether it is engaged in an unrelated trade or business.

A section 501(c)(3) organization may form and participate in a partnership, including an LLC treated as a partnership for federal income tax purposes and meet the operational test if participation in the partnership furthers a charitable purpose and the partnership arrangement requires the exempt organization to act exclusively in furtherance of its exempt purpose and only incidentally for the benefit of the for-profit partners.

To meet the operational test, the ACO must function to advance the tax-exempt partner’s charitable purpose of providing community benefit, which could include community health improvement services to meet needs identified in the tax-exempt hospital partner’s CHNA and prioritized in its CHIP. An ACO’s charitable purpose can also be advanced through activities related to Medicaid and indigent populations.

To meet the organizational test a tax-exempt organization may share 50/50 in an ancillary joint venture, e.g., an ACO, with a for-profit independent physician practice entity (or entities), without jeopardizing its tax-exempt status and without incurring unrelated business taxable income on its share of joint venture income if the activity conducted by the joint venture is substantially related to the exercise and performance of its tax-exempt purposes. Therefore, all contracts entered into by the LLC joint venture should be at arm’s length and for fair market value. In addition, the ownership interests of the participants in the joint venture must be proportional to their respective capital interest investments.

Contributions to the LLC and allocations of profits, losses and distributions must be made in proportion to the interests of the members. The ACO LLC’s governing documents must commit the LLC to provide healthcare services, e.g., activities advancing the Triple Aim, for the benefit of the community as a whole and to give charitable priorities over maximizing profits for the LLC’s owners.

**UBI Relative to Tax-Exempt Hospital ACO Members**

Section 511 of the IRC imposes a tax on the UBI of organizations described in section 501. UBI is taxable at corporate income tax rates which range from 15 percent on the first $25,000 of taxable income to 34 percent for taxable income over $75,000 with a maximum rate of 35 percent for taxable income over $10 million. If an ACO’s activities are not substantially related to a charitable purpose, they could generate UBI tax for its tax-exempt participants.

In the case of an ACO, certain MSSP and non-MSSP activities may be substantially related to the exercise or performance of a charitable purpose. In addition, the activities of tax-exempt participants in ACOs treated as partnerships, i.e., as an LLC, are attributable to the tax-exempt hospital for purposes of determining whether the hospital is engaged in an unrelated trade or business. If those activities are substantially related to the charitable purpose of promoting health, then the hospital’s participation in the LLC won’t impose UBI tax liability on the hospital. If, however, the ACO LLC is operated for the private benefit of private parties rather than the community as a whole, then the hospital’s participation could result in UBI subject to section 511 UBI tax.

ACOs conducting both MSSP and non-MSSP activities must be cognizant of UBI tax implications for their tax-exempt hospital participants. The IRS recognizes that generally non-MSSP activities substantially related to a tax-exempt participant’s charitable purposes will not generate UBI for that participant. Thus, if the ACO can demonstrate, as discussed above, that the non-MSSP activities are substantially related to a charitable purpose, e.g., being related to serving Medicaid or indigent populations or activities carried out to improve community health (community health improvement services), then UBI would not be attributed to the tax-exempt ACO participant.

Tax-exempt participants in ACOs treated as partnerships are guided by Rev. Rul. 2004-51 relative to their ownership interests and UBI exposure. For the tax-exempt participants to retain their tax-exempt status and avoid unrelated business income tax, for non-MSSP activities the community health improvement activities of the ACO must be shown to be similar to the community health improvement activities of the tax-exempt hospital. The hospital should demonstrate that the ACO LLC expands the reach of its population health/community health improvement efforts. The manner in which the LLC ACO conducts its community health improvement initiatives must contribute importantly to the accomplishments of the hospital’s charitable purposes (i.e., its community benefit) and its activities substantially related to those purposes in order for the hospital to not be subject to taxation of its distributed share of UBI under section 511. It should be noted that to date there are no published IRS revenue rulings, private letter rulings or investigations relative to ACO UBI attribution.

*continued on page 24*
Vermont All-Payer Model

The State of Vermont has partnered with CMS to develop an All-Payer ACO Model that commenced January 1, 2017. Under this model Medicare, Medicaid and commercial health payers will incentivize healthcare value and quality under the same payment structure for a majority of providers throughout the state. This voluntary program prioritizes outcomes specific to substance abuse, suicide, chronic conditions and access to care, i.e., Triple Aim goals.

The program provides Vermont clinicians startup funding of $9.5 million to promote care coordination and collaboration. CMS has approved a five-year extension of Vermont’s section 1115(a) Medicaid demonstration, allowing Medicaid to be a full partner in the ACO. The demonstration program will end on December 31, 2022, at which time the state intends to have 70 percent of all insured residents, including 90 percent of Vermont Medicare beneficiaries, covered by an ACO.

The Vermont All-Payer ACO Model represents advancement in CMS’ partnerships with states by bringing statewide healthcare transformation beyond the hospital by implementing payment and care delivery reform across all major payers throughout the state. To date, Vermont is the only state participating in this CMS All-Payer ACO Alternative Payment Model (“APM”) although CMS continues to seek information on potential additional opportunities to partner with states on payment and care delivery reform. It should be noted that new innovative ACO models, when introduced on a larger scale, will likely require the same tax analysis as other ACOs if nonprofit providers are participant members.

Next Steps for ACOs Planning to Participate in Non-MSSP Activities

As IRS guidance is limited, ACOs planning to participate in non-MSSP activities should utilize their nonprofit hospitals’ CHNA to identify community health improvement priorities. Evidence-based interventions can be selected from established public health resources commonly utilized by hospitals and health systems in their CHIPS. Consistent with their nonprofit hospital participants, ACOs can develop and implement program plans, utilizing evidence-based interventions to improve the health of their communities, thus directly benefiting the community as a whole.

Implementation plans identify problems being addressed, target populations, goals and objectives, resources, funding sources and program impact evaluation design. Community health improvement services can thereby provide evidence that ACO non-MSSP activities directly benefit the community as a whole. And in contrast to the ACO in PLR 201615022, any private benefit to physician members could arguably be qualitatively and quantitatively incidental in comparison to the community benefit produced by the ACO non-MSSP activities.

Conclusion

ACO market penetration is expected to increase throughout the Unities States and tax-exempt hospitals and independent physician groups will continue to organize and operate ACOs. If ACOs are going to succeed, then their nonprofit components, which comprise the backbone of these entities, need to protect their tax-exempt status in order to remain viable. Participation in Medicaid shared savings programs, partnerships with CMS in future all-payer state programs and greater participation in community benefit activities, services and programs can enhance the likelihood of ACOs being recognized as section 501(c)(3) tax-exempt organizations.

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Endnotes

Medicare Fact Sheet, Medicare Accountable Care Organizations 2015 Performance Year Quality and Financial Results, August 8, 2015, https://www.cms.gov/Newsroom/Media%20ReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-08-23.html. Section 1899 of the Social Security Act, as amended by section 3202 of PPACA, established the MSSP that promotes accountability for care of Medicare beneficiaries, improves the coordination of Medicare fee-for-service items and services, and encourages investment in infrastructure and redesigned care processes for high quality and efficient service delivery. Under this program, groups of providers of services and suppliers that meet criteria specified by CMS may work together to manage and coordinate care for Medicare fee-for-service beneficiaries through an ACO. If an ACO meets quality performance standards and demonstrates that it has achieved savings against a benchmark established by CMS, it will be eligible to receive payment from CMS equal to a portion of the total savings (Shared Savings). IRS Fact Sheet, Tax-Exempt Organizations Participating in the Medicare Shared Savings Program Through Accountable Care Organizations, FS-2001-11, October 20, 2011, https://www.irs.gov/pub/irs-news/fs-2011-11.pdf.


The IRS in PLR 201145025 similarly denied an exemption for a hospital-owned organization formed as a nonprofit corporation whose primary activity was to establish and participate in a health delivery network. In that instance the organization negotiated and entered into payer agreements with purchasers of physician medical services for subscribers of a benefit plan (e.g. health maintenance organizations, preferred provider organizations and other arrangements), employers, insurance carriers, third-party employee benefit plan administrators, self-funded plans and groups, and similar organizations) under which it was obligated to provide or arrange for the provision of such medical services. This “messenger model” network, whereby the organization acted as a vehicle for communicating fee schedule offers to participating physicians and participating physicians’ counteroffers to insurers, was found, like the HMO described in Geisinger Health Plan vs. Commissioner of Internal Revenue, 985 F.2d 1210 (1993), to not provide health services directly but merely facilitated negotiations on behalf of physicians on the hospital medical staff to provide medical services to consumers of those services. As the court held in Geisinger Health Plan, the IRS in PLR 201145025 concluded that the organization’s primary activity was not charitable within the meaning of section 501(c)(3). The organization failed to meet the organizational test under section 1.509(a)(4) of the regulations, the operational test under section 1.509(a)(4), the operational test under section 1.509(a)(4), i.e., as a supporting organization. See PLR 201145025, November 10, 2011, https://www.irs.gov/pub/irs-wd/1145025.pdf.

Section 501(a) provides that an organization described in subsection (c) or (d) or section 401(a) shall be exempt for taxation under this subtitle unless such exemption is denied under section 502 or 503. Subsection (c)(3) identifies organizations referred to in subsection (a) to include corporations, and any community chest, fund, or foundation organized and operated exclusively for a religious, charitable, scientific, or educational purpose. See https://www.law.cornell.edu/uscode/text/26/501.


Restatement (Second) Trusts, sections 368 and 372 (1959); IV Scott on Trusts (3rd ed. 1967), sections 368 and 372.


Id., page 79.

IRS, 1990 EO CPE Text, C. Overview of Inurement/Private Benefit issues in IRC 501(c)(3), V.

Fishman and Schwarz, supra page 207.

Medicare should not be reported as a community benefit. Medicare is not a means-tested program and is not included in the means tested category of community benefit. Medicare-funded programs are reportable as subdirected health services and in health professions education and research categories. Other Medicare revenues (for MSSP ACOs, the payer is Medicare) and costs may be reported on Parts III (Bad Debt, Medicare and Collection Practices) and IV (Management Companies and Joint Ventures) of Schedule H but not as community benefit. See A Guide for Planning and Reporting Community Benefit, The Catholic Health Association of the United States, 2015, page 47.


A business entity that is not classified as a corporation under section 301.7701-2(b)(1), (3), (4), (5), (6), (7), or (8) (an eligible entity) can elect its classification for federal tax purposes as provided in this section. An eligible entity with at least two members may elect to be classified as either an association (and thus a corporation under section 301.7701-2(b)(2)) or a partnership, and an eligible entity with a single owner may elect to be classified as an association or to be disregarded as an entity separate from its owner, section 301.7701-3(a), https://www.law.cornell.edu/cfr/text/26/301.7701-3. A disregarded entity, as described in sections 301.7701-1 through 301.7701-3, is generally treated as a branch or division of its parent organization for federal tax purposes. Therefore, financial and other information applicable to a disregarded entity must be reported on the parent organization’s information, except on Form 990, Part VI (Governance, Management and Disclosure), lines 10(a) and 10(b) [Policies as to whether the organization has local chapters, branches or affiliates and whether the organization has written policies and procedures governing the activities of such chapters, affiliates and branches to ensure their operations are consistent with the organization’s exempt purpose] and on Schedule R (Form 990) [Related Organizations and Unrelated Partnerships, Part I-Identification of Disregarded Entities] in which disregarded entities must be separately reported. See IRS 2016 Instructions for Schedule H (Form 990), page 81, https://www.irs.gov/pub/irs-pdf/990p.pdf. For example, an LLC with only one member is generally disregarded for federal income tax purposes.


Section 501(r) was added to the IRC by PPACA and imposes additional requirements on charitable hospital organizations. Section 501(r)(1) provides that a hospital organization described in section 501(r)(2) will not be treated as a tax-exempt organization described in section 501(c)(3) unless the organization meets the requirements of sections 501(r)(3) through 501(r)(6). Section 501(r)(3) requires a hospital organization to conduct a community health needs assessment (“CHNA”) at least once every three years and adopt an implementation strategy to meet the community health needs identified through the CHNA, https://www.law.cornell.edu/uscode/text/26/501.

4 Hospitals are required in their CHNA to identify health priorities for their Community Health Implementation Plan (“CHIP”). The CHIP must explain the activities the hospital intends to undertake to address the health needs identified through the CHNA. The hospital prioritizes the needs on the basis of whatever process and criteria it decides while involving the community. The hospital must then explain on Schedule H, Part VI, how it will address the community health needs deemed to be priorities. Evadwick, Connie J., Hospitals & Community Benefit, New Demands, New Approaches, Health Administration Press, 2013, page. 41. For most hospitals, its internal assessment team, the assessment advisory committee and key partners identify preliminary priorities. Key partners might include public health officials, other service providers and community members and leaders. Priorities should be shared with the hospital board and executive leadership and others in the community for validation and consensus. The Catholic Health Association of the United States, supra, page 161. Once those priorities are determined the hospital identifies evidence-based health improvement intervention programs. In assessing community health needs Treas. Reg. 1.501(r)-3(b)(4) notes that health needs identified in the CHNA may include the need to address financial and other barriers to

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27 These requirements include the following: (1) the terms of the tax-exempt organization’s participation in the MSSP through the ACO (including its share of MSSP payments or losses and expenses) are set forth in advance in a written agreement negotiated at arm’s length; (2) CMS has accepted the ACO into, and has not terminated the ACO from, the MSSP; (3) the tax-exempt organization’s share of economic benefits derived from the ACO (including its share of MSSP payments) is proportional to the benefits or contributions the tax-exempt organization provides to the ACO; (4) if the tax-exempt organization receives an ownership interest in the ACO, the ownership interest received is proportional and equal in value to its capital contributions to the ACO and all ACO returns of capital, allocations and distributions are made in proportion to ownership interests; (5) the tax-exempt organization’s share of the ACO losses (including its share of MSSP losses) does not exceed the share of ACO economic benefits to which the tax-exempt organization is entitled; and (6) all contracts and transactions entered into by the tax-exempt organization with the ACO and the ACO’s participants, and by the ACO with the ACO’s participants and any other parties, are at fair market value. IRS Notice 2011-20, pages 7 and 8, March 31, 2011, https://www.irs.gov/pub/irs-drop/n-11-20.pdf. The IRS later clarified in FSA 2011-11, page 6 that no particular factor must be satisfied in all circumstances to prevent inference or impermissible private benefit, https://www.irs.gov/pub/irs-news/fs-2011-11.pdf.


30 Id., page 3.

31 Id., page 4.

32 Id.

33 Id., page 5.

34 IRS Notice 2011-20 supra page 1.


36 IRS FS 2011-11 supra pages 3, 4, and 5.

37 “The Institute for Healthcare Improvement (“IHI”) Triple Aim is a framework that describes an approach to optimizing health system performance. The IHI believes new designs must be developed to simultaneously pursue three dimensions, i.e., the Triple Aim. The IHI developed a concept design and described an initial set of system components to fulfill the Triple Aim in 2007. The five components include a focus on individuals and families, redesign of primary care services and structures, population health management, cost control platform, and system of integration and execution, The IHI Triple Aim, The Institute for Healthcare Improvement, http://www.ihi.org/engage/initiatives/TripleAim/Pages/default.aspx.


41 IRS PLR 201615022 supra page 9.


46 The Pioneer ACO Model was designed for healthcare organizations and other providers that were already experienced in coordinating care for patients across care settings. It allowed these provider groups to move more rapidly from a shared savings payment model to a population-based payment model on a track consistent with, but separate from, the MSSP. It was also designed to work in coordination with private payers by aligning provider incentives, which improved quality and health outcomes for patients across the ACO, and achieved cost savings for Medicare, employers and patients. The Pioneer ACO Model with 32 ACOs in 2012 and concluded December 31, 2016 with eight ACOs participating, Pioneer ACO Model, Center for Medicare and Medicaid Innovation, https://innovation.cms.gov/initiatives/Pioneer-ACO-Model/.

47 Within the community profile section of the survey, ACOs were asked whether their ACO completed a CHNA. Those ACOs responding affirmatively were (1) a partnership of a hospital, (2) owned by a health system, (3) owned by a hospital, or (4) affiliated with a hospital. So while the ACOs themselves were not required to complete CHNAs, their respective hospitals and hospital systems were, noting the collaborative nature of the CHNA process. Written responses included the following: “In our area there’s ourselves, a competitor hospital that’s of similar size and then a FQHC clinic and the three facilities have coordinated together and formed... it’s called the (name). So, there are various interventions that we work on as a group for improving access to community resources. We have a Community Crisis Center, which is for those with either mental illness or substance abuse issues. It’s not a homeless shelter and it’s not the emergency room, it’s kind of somewhere in between to kind of help bridge people out of the hospital that don’t necessarily have access to resources, ectcets, so that they are not on the street. And then, we do a community health needs assessment I think on an 18-month cycle as an Alliance and then the Alliance has sought out research and grant funding, various things over time.” Premier Inc., supra page 35. “I think part of the work with our community health needs assessment would be a good example that instead of being in isolation with everyone completing their own assessment the work that’s in place to get us to all come together and achieve one assessment and one action plan.” Premier Inc., supra page 63.

48 Id., page 15.

49 A 2015 study using 2009 data from hospital Form 900 filings of 1,522 private, tax-exempt hospitals and 2010 County Health Rankings revealed that expenditures on direct patient care benefits accounted for most of hospitals’ total spending on community benefits (6.3% of total hospital expenditures on direct patient care vs. 6% of total hospital expenditures on community health improvement initiatives). However, recent policy developments and industry trends have the potential to influence hospital spending priorities on community benefits that may strengthen the relationship between community benefit expenditures and community health needs. Payment reforms found in the MSSP and a growing number of initiatives by Medicaid programs as well as private health plans combine spending and quality targets for healthcare providers who assume financial and clinical responsibility for a defined population. This shift from volume-based payment to value-based payment may result in more hospital prioritization of community health initiatives, particularly among hospitals in communities with a relatively high incidence of chronic illness, because hospitals will have financial incentives to reduce service utilization for individuals for whom they are responsible. Singh, Souna B., Young, Gary J., Shou-Yih, Daniel Lee, Song, Paula, Alexander, Jeffry A., Analysis of Hospital Community Benefit Expenditures’ Alignment...


51 The LLC joint venture’s articles of incorporation and operating agreement provided that the LLC joint venture would be managed by a governing board consisting of three individuals chosen by the nonprofit member and two individuals chosen for the for-profit member. The nonprofit member intended to appoint community leaders who had experience with hospital matters, but who were not on the hospital staff and did not otherwise engage in transactions with the hospital. IRS Rev. Rul. 98-15, page 2, https://www.irs.gov/pub/irs-drop/r98-15.pdf.

52 Under the operational test of Treas. Reg. 1.501(c)(3)-1(c)(1) – Primary Activities – an organization will be regarded as operated exclusively for one or more exempt purposes only if it engages primarily in activities which accomplished one or more exempt purposes specified in section 501(c)(3). See https://www.law.cornell.edu/cfr/text/26/1.501%28c%29%283%29-1.

53 In the absence of a binding obligation in the LLC joint venture’s governing documents for the LLC to serve charitable purposes or otherwise provide its services to the community as a whole, the LLC would be able to deny care to segments of the community, such as the indigent. Because the nonprofit member would share control of the LLC with the for-profit member, the nonprofit member would not be able to initiate programs within the LLC to serve new health needs within the community without the agreement of at least one governing board member appointed by the for-profit member. As a business enterprise, the for-profit member would not necessarily give priority to the health needs of the community over the consequences for the LLC’s profits. IRS Rev. Rul. 98-15, page 17.


55 Section 511(a), in part, provides for the imposition of tax on the unrelated business taxable income (as defined in section 512) of organizations described in section 501(c)(3), supra, page 2.


57 “An Institution for the promotion of health is not a charitable institution if it is privately owned and run for the profit of its owners,” Rev. Rul. 98-15. PLR 201615022, supra, page 5.


59 Under the operational test of Treas. Reg. 1.501(c)(3)-1(c)(1) – Primary Activities – an organization will be regarded as operated exclusively for one or more exempt purposes only if it engages primarily in activities which accomplished one or more exempt purposes specified in section 501(c)(3).


63 Section 512(a)(1) defines unrelated business taxable income as the gross income derived from any unrelated trade or business regularly carried on, less the allowable deductions that are directly connected with the carrying on of the trade or business computed with certain modifications. Section 512(c)(1) provides that if a trade or business regularly carried on by a partnership of which an organization is a member is an unrelated trade or business, this organization in computing its unrelated trade or business taxable income must include its share of the partnership’s gross income and deductions directly connected with gross income. Section 512(c)(1) applies as well to LLCs treated as partnerships for federal income tax purposes. Section 513 defines unrelated trade or business as a trade or business the conduct of which is not substantially related to the exercise or performance by such organization of its tax-exempt purpose. See https://www.law.cornell.edu/uscode/text/26/1.513-1(a).

64 IRS FS 2011-11, supra, page 4.

65 The Vermont All-Payer ACO Model is an exciting advancement in CMS’ partnerships with states to accelerate delivery system reform. CMS has been partnering with Maryland since 2014 as part of the Maryland All-Payer Model to shift hospital payments to global budgets that reward value over volume. The Vermont All-Payer ACO Model builds on the Maryland All-Payer Model by bringing statewide healthcare transformation beyond the hospital. This Model will provide valuable insight for other opportunities for CMS to participate in state-driven all-payer payment and care delivery transformation efforts. On September 8, 2016 CMS released a request for information on concepts related to state-based payment and delivery system reform initiatives. Vermont All-Payer ACO Model, Centers for Medicare & Medicaid Services, https://innovation.cms.gov/initiatives/vermont-all-payer-aco-model.


67 Vermont All-Payer ACO Model, Centers for Medicare & Medicaid Services, supra.


Be Part of the Health Law Section Delegation to Cuba in March 2018

See the Cuban healthcare system firsthand as a member of the ABA Health Law Section Delegation to Cuba, March 26–31, 2018. The delegation will spend five days in and around Havana touring healthcare facilities and participating in discussions with Cuban healthcare professionals and administrators as well as members of the Cuban legal community.

Meet with your Cuban counterparts to learn about challenges and advances in healthcare and health law in Cuba. Delegate interests will be taken into account in determining the final topics that will be covered; however, a sample of the topics includes:

- Overview of the healthcare system in Cuba
- Access to healthcare and patient rights
- Current issues facing the healthcare system
- Overview of the Cuban legal system
- The role of the legal system in relation to the healthcare system

In addition to the healthcare and law-related activities there will also be opportunities to experience Cuban cultural activities (art, music, dance, history, food). Our accommodations will be at the MeliaCohiba in Havana (a great hotel). March is also a fine time to visit with good weather and moderate temperatures.

The estimated cost per delegation member is $4,895. This includes essentially all expenses associated with participation. To view the itinerary and other program details, visit ambar.org/hlscuba.

You have likely heard of the Administration’s Travel Advisory as to Cuba. However, to the best of our knowledge (and confirmed by our trip organizers, Academic Travel Abroad) there has not been a single case of injury or illness to travelers related to the illness at the American Embassy. It is also worth mentioning that Havana has significantly less street crime than most American cities.

We strongly encourage you to sign up at ambar.org/hlscuba no later than December 15, 2017, and join us on this exciting opportunity. You may also speak with a Reservations Specialist at 877.298.9677 to have questions answered and complete enrollment. Cuba is calling! We believe that this experience will be both personally and professionally rewarding.

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The Health Law Section of the American Bar Association is pleased to announce the Fifth Annual Scholarship Program for law students interested in the health law field to attend the Emerging Issues in Healthcare Law Conference from February 21–23, 2018 in Scottsdale, Arizona.

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The deadline to submit an online application is December 15, 2017.

If you have any questions or concerns, please contact Simeon Carson, Director, at simeon.carson@americanbar.org.

To apply, visit ambar.org/EMI2018.
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HEALTHCARE PROFESSIONALS ENCOUNTER HURDLES WHEN FACED WITH NEGATIVE REVIEWS ON SOCIAL MEDIA

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Introduction

The recent proliferation of online review websites in recent years has caused business owners of all types to rethink the way in which they manage their image in the perilous landscape of social media. Sites such as Google, Yelp, Ripoff Report and countless others have provided a quick and easy venue for unsatisfied patrons to vent their frustrations, often at a time when they are at their most incensed and unreasonable, and immediately after they might feel they have been slighted.

Doctors, dentists, psychologists and other healthcare professionals have not remained insulated from these issues. Indeed, medical professionals face an even more labyrinthine set of challenges, due to issues such as healthcare privacy laws and other considerations of clinician-patient confidentiality. Additionally, the services offered by healthcare providers, and the relationships between providers and patients, are typically of a more sensitive and potentially volatile nature. An accusation of medical malfeasance by a former or current patient in a social media review can carry far more detrimental implications than the complaints of a restaurant patron that his steak was not cooked to his liking.

Whether the new reality of online customer reviews constitutes a positive or negative development is a subject on which reasonable minds could differ. The question remains, however, as to what recourse a healthcare professional has when faced with a negative review which could tangibly impact her business and reputation.1

Can a Practitioner File Suit Against the Review Website?

To a medical professional facing a negative social media review, the most facially reasonable course of action might be to file a defamation suit against the website hosting the social media review in an attempt to force it to take it down. Unfortunately, the United States legislature foresaw the potentially massive liability to which such sites such as Yelp and Google might be exposed if they were held responsible for content posted by users, thus enacting the Communications Decency Act of 1996 (“CDA”).2 Although the CDA was originally intended to address the rapid proliferation of pornographic material on the internet, the provisions related to adult content were judged to be unconstitutional by the United States Supreme Court shortly after its enactment.3 Thus, the functional remainder of the CDA serves to immunize interactive computer service providers from lawsuits based on the false or defamatory statements contributed to their websites by others.4

Section 230 of the CDA states that “[n]o provider or user of an interactive computer service shall be treated as the publisher or speaker of any information provided by another information content provider.”5 Furthermore, the CDA preempts all conflicting laws that might favor a plaintiff by stating that “[n]o cause of action may be brought and no liability may be imposed under any State or local law that is inconsistent with this section.”6 “Interactive computer service” is defined under the statute as “any information service, system or access software provider that provides or enables computer access by multiple users to a computer server.”7

An internet computer service is, however, liable for its own speech or for its material contributions to the content of a third party’s statements because, in that case, it is serving as an “information content provider.”8 An “information content provider,” as defined by the CDA, is “any person or entity that is responsible, in whole or in part, for the creation or development of information provided through the internet or any other information computer service.”9 While this may sound promising to a prospective plaintiff, third party review websites rarely, if ever, contribute anything to the actual substance of a review before allowing it to be posted on their website, and hence remain insulated from liability by aggrieved business owners.10

Does the Prioritization of Positive or Negative Reviews Expose the Website to Liability?

In one case, Levitt v. Yelp, the plaintiffs attempted to argue that Yelp had abrogated its immunity under the CDA because it prioritized the publication of negative reviews while refusing to publish positive ones, thereby having a detrimental effect on a business’s reputation.11 In prioritizing negative reviews, it was maintained, Yelp was attempting to coerce the businesses into buying paid advertising with Yelp to improve their online image.12 Because of this, the plaintiffs argued, Yelp’s actions were “business related” rather than simply “editorial” and not entitled to protection under the CDA because they were a de facto internet content provider.13

The court in Levitt, and all other courts that have addressed the matter,
The posting of negative reviews over positive ones, according to the court, did not provide an exception to that entity's protection as an "interactive computer service" provider because the posted data was still third party content and was not manipulated by Yelp. With respect to the alleged refusal to post or prioritize positive reviews, the court in Levitt stated that there is no pre-existing right to positive reviews on the part of an interactive computer service.

Other courts have more broadly clarified that "lawsuits seeking to hold a service provider liable for its exercise of a publisher's traditional editorial functions – such as deciding whether to publish, withdraw, postpone or alter content – are barred." In other words, the prioritization of certain content of even the withholding of positive reviews falls under the auspices of a website's editorial discretion and cannot form the basis for a cause of action against it.

The bottom line is that online review websites are effectively insulated from suit under the CDA. State law provisions which might expose them to liability on similar grounds, as stated earlier, are preempted by the CDA and reliance on them has proved unsuccessful in litigation.

What Should the Plan of Action Be?

Upon first witnessing a negative review left by a patient, a healthcare professional's most likely initial reaction could be anger directed at the patient, sadness that he had been construed as having not provided a high quality of care, or fear that his practice might suffer in the face of such deleterious and highly visible criticism of his professional competence.

There are, however, actions that can be taken to mitigate the impact of poor reviews, both through the legal system and by other means.

Pursue All Available Recourse Through the Review Websites

Although a healthcare professional cannot force a website such as Google or Yelp to remove a negative review by filing a lawsuit against the website, many sites include at least some modicum of procedure to which a person or business on the receiving end of the review may resort.

RateMDs, for instance, allows the medical practitioner to claim her profile, meaning that she can inform the website that the profile belongs to her and add missing data to form a more complete picture of her as a practitioner. Once claimed, the practitioner can flag any reviews that might be either fake or posted by one person multiple times in an attempt to drive down the practitioner's rating. Flagging the reviews will cause the website to investigate whether they are clearly fake or written by the same person in violation of the site's terms of service. RateMDs also allows a practitioner to hide up to three reviews from the main page, although the numerical rating assigned to the reviews will still be reflected in the clinician's "star" rating.

In a recent instance, a prospective client, a psychologist, was besieged by multiple inflammatory reviews posted by a mentally-ill former patient, which drove her RateMDs star rating from five stars down to two. The reviews were clearly all authored by the same person, extremely hostile in tone and contained such bombastic accusations concerning the psychologist's behavior and competence that they were clearly outside the realm of credibility. Assuming the integrity of the flagged-review process, reviews such as these should easily be taken down without any additional action. In fact, through nothing more than the use of this process, the aforementioned client was able to restore her rating back to five stars.

Google, Yelp, WordPress and other websites all have similar mechanisms to flag false or abusive posts and reviews. Although these websites cannot be relied upon to remove all content that a reviewed party might find unpleasant, it is more than worthwhile to take the time to find out what each site's avenue of recourse is and try to work with it to the most effective degree possible.

Reach Out to the Patient Who Left the Negative Review

The ultimate power to remove a negative review rests, for better or worse, with the aggrieved patients themselves. As the author of the review, the patient could likely remove it with nothing more than a few clicks. Despite the inherent appeal of that thought, extreme caution should be taken when considering the manner in which this should be approached with the patient, or whether it should be approached at all. Even though a clinician might believe he is in the right, a patient clearly does not see it that way if the patient felt strongly enough to air her grievances on social media. A careful appraisal of the situation should be made in determining whether or not a patient would be receptive to an invitation from the clinician to right the actual or perceived wrong that the patient feels has been done to her. Practitioners would be wise to consider the substance of the patient's complaint and the length and nature of the relationship with the patient up to that point.

Even if a patient is receptive to any attempts by a clinician at reconciliation, the remedies the clinician can offer may be limited. For example, if a patient complained about a rude receptionist or member of the support staff, a healthcare professional could offer his sympathies and promise to deliver better service in the future. The practitioner must be extremely careful, however, before offering anything to a patient that might be construed as having monetary value. While there might be some latitude if a patient is paying for

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services out-of-pocket, a waiver of deductibles or copayments where federal health insurance programs (such as Medicare or Medicaid) are concerned can implicate both the Civil Monetary Penalties Law and the Anti-Kickback Statute, and land a clinician in serious trouble. The routine waiver of copayments also violates the guidelines of many private insurers and has been declared by the American Medical Association to be an unethical practice.

**Encourage Other Patients to Leave Positive Reviews**

While a negative review can stand out like a sore thumb on an otherwise clean record, a healthy number of positive reviews can go a long way towards mitigating the harm that a negative review may cause. Positive reviews further serve the purpose of making a negative review seem like an isolated incident or simply the product of an unreasonable patient, rather than evidence of a practitioner's substandard care.

Because healthcare services can be of a more sensitive and personal nature than those of restaurants or auto mechanics, special care should be taken in encouraging patients to leave reviews. Generally, clinicians could approach the patients who are loyal and well-known and simply ask for a review. It also goes without saying that providing the highest possible quality of care and attention will go a long way towards ingratiating patients to a clinician to the point where they would want to share about it on social media. Finally, clinicians should provide patients with a quick and easy method of leaving a review, such as a direct link to a review website in standard email communications.

However, for the purposes of receiving reviews specifically on Yelp, note that Yelp has recently adjusted its policies and guidelines with respect to soliciting reviews from patrons of one's business. As of this writing, Yelp specifically instructs business owners not to ask for reviews. Yelp's reasoning behind this prohibition stems from a desire to see its reviews represent an accurate cross-section of customer opinion and, in its view, solicited reviews create bias which skews actual public perception of the business. Business owners that run afoul of Yelp's policies run the risk of either having their account deactivated or the placement of a “Consumer Alert” on their Yelp page. A Consumer Alert is a popup which appears over the business owner's Yelp page when visited, informing the visitor that the business has been flagged for manipulating or attempting to manipulate its Yelp rating.

Yelp also uses sophisticated software to determine which reviews are solicited and mark them as “Not Recommended,” which means that they get pushed off the main page and not factored into a business’s star rating. This prohibition extends to related behaviors such as offering incentives to patients for leaving reviews on Yelp, or offering additional compensation to employees for generating positive reviews. Although – for the moment – only Yelp has a prohibition on solicited reviews, any practitioner with a presence on social media should be cognizant of changing norms in this area, lest one's practice of asking for reviews on sites other than Yelp becomes similarly forbidden.

Despite Yelp's stance on the matter, it should be noted that it remains lawful to ask a patient to write a genuine positive review, but one cannot contractually prohibit a patient from writing a negative review. By way of example, a fertility clinic in California required its patients to sign a contract stating that the patient would not leave negative reviews regarding the practice. Despite being located in California, the clinic provided nationwide egg donation services, and the validity of the contract clause was challenged by the state of New Jersey, which deemed the clause to be in violation of the New Jersey Consumer Fraud Act and thus unenforceable.

In a separate case, a dentist attempted a different and more novel approach to the issue by requiring her patients to sign an agreement prior to treatment stating that they would refrain from publishing commentary related to the dentist's practice and, if they did choose to publish such commentary, that the intellectual property rights and copyrights to the published content would belong to the dentist. A lawsuit ensued when one of the dentist’s patients posted negative reviews in spite of the agreement, and the agreement was struck down by the court, which cited a misuse of copyright law and a violation of dentists’ ethics among the reasons why the agreement was legally invalid.

Further undermining any attempt to limit negative reviews through contract, President Obama subsequently signed into law the Consumer Review Fairness Act, which imposed a blanket invalidity to all contractual terms going forward that seek to suppress the posting of negative reviews on the internet.

Finally, clinicians should be extremely wary of “reputation management firms,” as such firms will often take it upon themselves to violate the terms of service of internet review sites by submitting fake reviews. One such company has even been accused of filing lawsuits against reviewers for defamatory content and finding a fake “defendant” to “admit” to posting the review so the company can obtain a court order to be served on Google so that the negative reviews are delisted from Google's search results. Additionally, an urgent care center in New...
York recently settled (for $100,000) a case brought by the New York Attorney General for paying internet advertising companies and others for positive reviews. A clinician should think long and hard before getting involved in this type of business.

Write a Demand Letter

If all of the above methods prove ineffective or insufficient, another prospective course of action would be to retain an attorney to draft and send a demand letter to the patient in the hope that this will convince him to take the review down.

Naturally, there is no guarantee that a demand letter will be effective. Particularly in the case of very angry or unreasonable patients, they might see the threat of legal action as a motivator to double down on whatever invective they were already dispensing. They might even go a step further and consider a suit for medical malpractice, whether or not the suit would ultimately be meritorious. As one website points out, a demand letter can also backfire in that there is nothing to prevent a patient from publishing the demand letter on the internet in order to paint the clinician as “bullying” the patient.

File Suit Against the Patient

If all else fails, the remaining course of action is to file a lawsuit against the patient. The main purpose of this lawsuit is typically not to obtain money damages (although this remains a possibility), but to secure a court order stating that the review is defamatory or otherwise unlawful. This order can then be served upon the sites that host the review in order to compel them to remove it.

Can the Patient Who Left the Review Be Successfully Sued?

The short answer to this question is, most accurately, “maybe.” However, the option of suing the reviewer and former patient brings with it several attendant issues.

Defamation

Any cause of action that might be brought against the reviewing patient would most likely be for written defamation (known as libel at common law). This is an action under state law and, as such, can vary from one state to another, but the basic elements of a claim for written defamation remain largely the same. By way of example, under New York law, a plaintiff must establish five elements to recover: (1) a written defamatory statement of fact concerning the plaintiff; (2) publication to a third party; (3) fault (either negligence or actual malice depending on the status of the libeled party); (4) falsity of the defamatory statement; and (5) special damages or defamation per se.

Most elements in cases such as these are easy to satisfy. That there is a written defamatory statement published to a third party is rarely a fact in contention, because there is a negative review plainly posted on a public website. Fault refers to the level of culpability in making a false statement; private citizens must prove at least negligence by the defendant in having made a false statement against them and public figures must prove intentional malice. Additionally, most defamation suits would require proof of damages, but there exists a concept of defamation per se, where statements which impugn a plaintiff’s trade, occupation or business are presumed to be damaging.

Of the five elements of defamation, the most problematic is the fourth. A suit for defamation cannot succeed unless the defamatory statements at issue are demonstrably false. As shown by the case law cited below, especially in the case of healthcare professionals, even inflammatory and damaging declarations regarding a clinician’s professional competence can fall short of this standard.

Prior Case Law

Although case law exploring this particular issue is still developing, there are several cases which are instructive. The New York case of Reit v. Yelp involved a dentist who sued Yelp, seeking an injunction against having his dental practice featured for reviews on the Yelp website. Owing to the principles stated above, the suit against Yelp was dismissed based on the applicable provisions of the CDA.

In another of the few cases in New York confronting the issue, one doctor sued another in Tener v. Cremer for posting a Vitals.com comment stating that the plaintiff was a “terrible doctor,” “mentally unstable” and had “poor skills” and advised prospective patients to stay away from her. Despite the inflammatory nature of the comments, the court characterized the defendant’s statements as mere statements of opinion which were protected by the First Amendment. This was bolstered, in the court’s view, by the fact that the Vitals.com terms of service expressly stated that its content was to be considered opinions rather than facts. Although reasonable minds could differ on the court’s interpretation, the case seems to stand for the proposition that, in New York at least, the threshold for victory in a claim for defamation based upon an online review is very high, indeed.

Supplementing Tener, the Minnesota case of McKee v. Laurion provides an example of a case dealing with an online review of a doctor by a patient’s family member. In that case, a patient’s son wrote negative comments with regards to the plaintiff-doctor who attended his father when he visited the hospital for a stroke. Of the six statements alleged to be defamatory (among them being the statement that the doctor left the room without talking to the patient’s family, and that a nurse had referred to the doctor as “a real tool”), the court ruled all of them to be either protected opinion, substantially true
or too vague to convey a defamatory meaning.\textsuperscript{38}

**HIPAA and Patient Privacy Considerations**

One option not discussed above when dealing with negative reviews, and one that should be used with great caution (if at all), is the option of responding directly to the reviewers through the website. Due to the federal Health Insurance Portability and Accountability Act (“HIPAA”),\textsuperscript{49} as well as state law confidentiality and privacy laws, any such attempt to rebut the claims in a review might cause a practitioner to inadvertently disclose protected health information.\textsuperscript{50} In fact, even disclosing that the reviewer was, in fact, a patient or that any part of what he is saying is based in the facts of his visit could be said to constitute a HIPAA violation.\textsuperscript{51} Any reply should be stated in the most general terms and in a respectful tone, so as to not run afoul of healthcare information privacy laws.\textsuperscript{52}

The same caution should be taken in filing a lawsuit. Even the bare facts of a legal complaint, coupled with the name of the defendant in the caption, are sufficient to constitute a HIPAA violation if they so much as acknowledge that the named individual was the recipient of specified medical services.\textsuperscript{53} States such as New York, however, permit the sealing of court records upon a showing of good cause.\textsuperscript{54} If a plaintiff wishes to commence an action that involves confidential information, he is required to submit a summons and complaint with the sensitive material redacted, an index number request form and an Request for Judicial Intervention form to the county clerk, who will refrain from processing the filing for two to three days so that a plaintiff can obtain a sealing order and a temporary restraining order sealing the file pending the request.\textsuperscript{55}

Other states have similar mechanisms for filing court documents that contain sensitive information. California, for instance, allows records to be submitted under seal by application or motion of a party along with the secure delivery of un-redacted versions of the documents to the court.\textsuperscript{56} In general, attorneys should look into the relevant court rules in their jurisdiction and otherwise take great pains to avoid the disclosure of protected health information whenever they are dealing with a matter that involves patient care in a public forum.

Note that, although a practitioner can be fined or cited for a HIPAA breach, no private right of action exists under HIPAA, so patients cannot personally sue over a HIPAA violation, although a state law may allow for a private right of action.\textsuperscript{57} According to some courts, however, a HIPAA breach can provide the standard of care in a negligence action when state law provides a cause of action for a healthcare provider’s alleged breach of its duty of confidentiality.\textsuperscript{58}

**What If the Identity of the Reviewer is Unknown?**

Although identity of the reviewer will often be a non-issue because patients either freely identify themselves when writing reviews or publish information that would lead them to be easily identified by the person who had treated them, in some instances a negative, or even fake, review is published and the writer remains unknown to the person or organization being reviewed. In this case, if the recipient of the negative review wished to pursue some recourse through the court, she might also wish to use the court to reveal the identity of a reviewer.\textsuperscript{59}

In one case, *Yelp v. Hadeed Carpet Cleaning*, the Virginia Court of Appeals held Yelp in contempt for refusing to comply with a subpoena to reveal the names of seven anonymous posters who left negative reviews of a carpet cleaning business. The plaintiff filed suit against seven anonymous authors of negative reviews, stating that it was convinced the reviewers were not actual customers of the business.\textsuperscript{60} Therefore, the reviews themselves were violative of Yelp’s own terms of service (which stated that posters must have been actual customers of the business before posting a review) and that the plaintiff was entitled to find out their identities in order to pursue some recourse against them for the negative effects on his business.\textsuperscript{61}

Although affirming that the right to anonymous freedom of speech does, indeed, exist under the First Amendment, the court stated that this right was not absolute and that defamatory (and thus unlawful) anonymous reviews were not permissible when they damaged a company’s reputation.\textsuperscript{62} The facts of the case were exceptional, and therefore it would be wise to construe the opinion narrowly in the context of revealing the identity of a reviewer. Throwing an additional wrench into any prospective reliance on *Hadeed* is the fact that the Supreme Court of Virginia ultimately reversed and remanded the case, stating that the trial courts did not have the power to enforce subpoenas issued in Virginia to obtain documents located in California.\textsuperscript{63}

It is also important to note that Virginia has developed its own statutory “unmasking standard” for obtaining the identities of anonymous persons on the internet, requiring the plaintiff show that the person the plaintiff is seeking to unmask has committed conduct which is may be tortious or illegal, or that the party requesting the subpoena has a legitimate, good faith basis to contend that it is the victim of “conduct actionable in the
jurisdiction where the suit was filed. The burden needed to unmask an anonymous poster varies along state lines, with some states using standards enumerated by either common law or local court rules, rather than statutes.

In general, most courts have viewed the issuance of a subpoena forcing a poster's identity to be revealed with disfavor. New York, for instance, shot down a plaintiff's attempt to reveal a poster's identity in the case of Sandals Resorts Int'l Ltd v. Google, Inc., relying on the high burden needed to facilitate pre-action discovery in demonstrating that a petition has a meritorious cause of action and that the information sought is material and necessary to the actionable wrong. In another case, Thomson v. Doe, the Court of Appeals of Washington rebuffed a lawyer's attempt to unmask the author of a poor review on Avvo, citing the high burden that a plaintiff needs to overcome in order to counterbalance free-speech considerations.

Ultimately, if the identity of a reviewer is unknown, the courts cannot be relied upon to obtain his identity. It should be noted that some websites, such as ZocDoc and AngiesList, have mechanisms in place to verify the identity of reviewers and confirm that they are, in fact, actual patients. Unfortunately, with the ubiquity of sites like Yelp, this is the exception rather than the norm. Clinicians who would attempt to unmask anonymous reviewers would also have to contend with the fact that the right to anonymous speech is explicitly considered protected under the First Amendment. This same protection has been explicitly extended to online speech.

**Conclusion**

There is some recourse available to doctors and other healthcare professionals faced with a negative review on social media. As previously stated, however, options can be limited and no course of action can ultimately ensure that a bad review will be taken down. Furthermore, there is no guarantee that the aggrieved clinician will have any effective legal recourse against either the patient or review website, although case law is still evolving. As with all business owners and other professionals that must contend with social media and its attendant issues, the best course of action from a proactive standpoint is to always ensure that the highest quality of care is provided and to remain vigilant of both the benefits and prospective pitfalls that online social media review websites have introduced to the business landscape.

**Endnotes**

1. The focus of this article is on healthcare practitioners, rather than institutional providers such as hospitals. This is not to say that institutional providers do not face some of the same issues, but they are generally more insulated from the effects of negative publicity by virtue of their larger size, relative lack of competition and considerable resources that can be devoted to public relations efforts. The growth of large provider networks through mergers and hospital acquisitions in recent years only serves to heighten this contrast.

2. 47 U.S.C. § 230. See also Robert Cannon, The Legislative History of Senator Exon's Communications Decency Act: Regulating Barbarians on the Information Superhighway, 49 FED COMM. LJ. 51 (1996) (wherein one of the sponsoring Senators of the bill declared that "[t]he information superhighway should not become a red light district").

3. Reno v. American Civil Liberties Union, 521 U.S. 844 (1997). Speaking for the Court, Justice Stevens reasoned that "[w]e are persuaded that the CDA lacks the precision that the First Amendment requires when a statute regulates the content of speech. In order to deny minors access to potentially harmful speech, the CDA effectively suppresses a large amount of speech that adults have a constitutional right to receive and to address to one another. That burden on adult speech is unacceptable if less restrictive alternatives would be at least as effective in achieving the legitimate purpose that the statute was enacted to serve." Id. at 874.


5. CDA § 230(c)(1).

6. CDA § 230(c)(3).

7. CDA § 230(f)(2).


10. Although CDA-based immunity sweeps broadly, there are a few exceptions. For instance, in the case of Anthony v. Yahoo, Inc., 421 F.Supp.2d 1257 (N.D. Cal. 2006), the plaintiff alleged that Yahoo created fake dating profiles of desirable singles in order to persuade users of Yahoo's dating service to renew their expiring subscriptions. Yahoo attempted to claim immunity under the CDA, but the court rebuffed the attempt, stating that if the allegations of the plaintiff were true, Yahoo was effectively creating its own content which could expose it to liability. Id. at 1262.

11. See Levitt v. Yelp! Inc., 765 F.3d 1123, 1127 (9th Cir. 2014).

12. Id.

13. Id. See also Reit, 907 N.Y.S.2d at 414.

14. See e.g., Levitt, 765 F.3d at 1127. Reit, 907 N.Y.S.2d at 415.


16. Levitt, 765 F.3d at 1133. The lack of a "pre-existing right" was dispositive in Levitt because a pre-existing right to a business opportunity or advantage was a necessary element of the plaintiff's cause of action for economic extortion under California's Hobbs Act. Id. at 1133.


18. Levitt, 765 F.3d at 1130-31, Reit, 907 N.Y.S.2d at 415 (refusing to hold Yelp liable for...
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deceptive advertising practices under § 349 of New York’s General Business Law.


22 Id.

23 Id.


28 Sollitto, supra note 25.

29 DON’T ASK FOR REVIEWS, supra note 26.


31 Id.


39 New York Times Co. v. Sullivan, 376 U.S. 254, 84 S.Ct. 710, 11 L.Ed.2d 686 (1964) (public figures must prove a higher level of culpability in defamation suits due to considerations of freedom of speech under the First Amendment).


41 Reit, 907 N.Y.S.2d 411 at 412.

42 Id. at 415.

43 Tener v. Cremer, 2012 WL 3230689 (N.Y. Sup. Ct.).

44 Id.

45 Id.

46 McKee v. Laurion, 925 NW 2d 725 (Minn. Sup. Ct. 2013).

47 Id. at 728.

48 Id. at 729.

49 See 45 C.F.R. § 160, 162, 162, et seq.


51 Id.

52 Id.


54 22 NYCRR § 216.1.


57 See 45 C.F.R. § 160, 162, 162, et seq.


60 Id. at 558.

61 Id.

62 Id. at 568.


70 In re Anonymous Online Speakers, 661 F.3d 1168, 1173 (9th Cir. 2011) (“the ability to speak anonymously on the Internet promotes the robust exchange of ideas and allows individuals to express themselves freely without ‘fear of economic or official retaliation...[or] concern about social ostracism.’”).
Disorders and Mental Health Interest Group and its Advisory Board, ably led this year by their respective Chairs, Greg Fliszar and Beth Ann Middlebrook. The HLS Council then approved the creation of a Committee on Health & Well-Being at its September 2017 meeting. The Charter for this Committee was developed by Lisa Genecov, Sidney Welch, Alexandria McCombs, and Kathleen DeBruhl, who are leading the Committee’s initial work.

What are these efforts about? When I first learned of these initiatives, I thought of them as focusing on “health and wellness.” But I was quickly educated on the differences between “wellness” and “well-being.” The terms “health and wellness” apply primarily to physical health, while “health and well-being” sweep broader, more holistically. The Task Force defines “lawyer well-being” in its report:

We define lawyer well-being as a continuous process whereby lawyers seek to thrive in each of the following areas: emotional health, occupational pursuits, creative or intellectual endeavors, sense of spirituality or greater purpose in life, physical health, and social connections with others. Lawyer well-being is part of a lawyer’s ethical duty of competence. It includes lawyers’ ability to make healthy, positive work/life choices to assure not only a quality of life within their families and communities, but also to help them make responsible decisions for their clients. It includes maintaining their own long term well-being. This definition highlights that complete health is not defined solely by the absence of illness; it includes a positive state of wellness.

*The Path to Lawyer Well-Being*, pp. 9-10.

What a wonderful state that describes! And we in the HLS have great resources, connections, and knowledge to bring our members to help enhance well-being. The new Committee is currently determining the scope and priorities for this first year. The Committee’s leaders are also reaching out to other ABA entities, not only the HLS’ own Substance Use Disorders and Mental Health Interest Group, but also CoLAP and the Task Force. Lawyer assistance programs have been doing important work for many years. The ABA Task Force, new Working Group, and new HLS Committee are bringing additional resources to bear to help lawyers be and stay well across the broad landscape of their lives.

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Introduction

With the rising costs of healthcare, many employers offer wellness programs to keep employees healthier. As part of workplace wellness programming, employers may offer employees wearable technology or other wellness applications or technology. For example, one recent survey found 35 percent of employers use wearable devices in their wellness programs.1

Companies that have made their mark in the wellness industry, such as through wearable technology, are beginning to move into developing clinical technology. In 2016 Fitbit publicized a push to transform itself into a “digital health company” that relies less on consumers and more on the healthcare industry.2 According to Fitbit’s chief executive officer (“CEO”), the goal is for Fitbit gadgets to monitor blood pressure, blood sugar and even diagnose disease.3 Other companies, such as Apple and Smartlife, seem to be jumping on that bandwagon, as well.4

Stepping into the world of diagnosing and treating disease, however, comes with a steep regulatory price. The rules that govern workplace wellness pale in comparison to the rules that govern medical care. Because insurance, including government insurance like Medicare and Medicaid, often pays for medical care, healthcare providers must navigate copious amounts of reimbursement rules both at the federal and state level. There are also malpractice and professional licensing issues that weigh heavily in everyday practice. There are rules that govern with whom providers may collaborate or employ, with whom they can share information (and how they can share that information), with whom they can share or waive fees for services, the meeting of quality standards, information submission requirements, information retention requirements, and more. A full discussion of the rules that govern health services delivery, such as the Health Insurance Portability and Accountability Act (HIPAA), fraud and abuse rules, or federal and state billing and licensing rules is beyond the scope of this article. However, it is important to recognize that these rules apply to healthcare delivery, and wellness companies that venture into healthcare will most likely need to contend with those rules.

The company Theranos provides a recent example of a high-tech startup falling prey to the staggering amount of regulation in healthcare. Theranos developed a laboratory test promising to detect hundreds of diseases requiring only one drop of blood and at a fraction of the costs of a conventional laboratory.5 Theranos began offering tests to the public in late 2013 and opened 42 blood-drawing wellness centers in Arizona, two in California and one in Pennsylvania.6 Most other blood-drawing centers are in Walgreens drugstores.7 The Centers for Medicare & Medicaid Services (“CMS”) sent a letter to Theranos on March 18, 2016 proposing sanctions against its leaders and taking away federal licensing for its laboratory facilities for continued failure to correct major problems with testing accuracy and competence.8 For example, Theranos failed to properly hire and train qualified people to run the testing machines, allowed unlicensed workers to review patient test results, failed to follow manufacturers’ instructions on equipment and did not have a proper, written protocol in place to calibrate the machines to maintain accuracy.9 Indeed, in July 2016, CMS banned Theranos’ CEO from owning or operating a medical laboratory for at least two years.10 The company also faces a fine of $10,000 for every day it is out of compliance.11

For wellness companies interested in developing technological devices or tools to market to the healthcare industry, there is also the specter of regulation by the Food and Drug Administration (“FDA”). It is the prospect of FDA regulation that is the focus of this article. Part of this technological revolution in medical care is known as “mobile health” or “mHealth,” which is the use of mobile communications devices like smartphones and tablet computers for health or medical purposes, usually for diagnosis, treatment, or simply well-being and maintenance.12 Most mobile health technologies interface with users through applications (“apps”) downloaded onto iPhones, iPads, or Android or Windows devices, for example.13 One aspiration of mHealth and other healthcare technology is to decentralize, demystify, and democratize medicine, shifting the locus of care away from expensive institutions like hospitals and towards individual patients.14 The push for medical clinicians to incorporate mHealth into their practices is increasing.15

As noted earlier, along with this increased interest by healthcare providers in mHealth or other wellness technology comes an increased likelihood of FDA regulation. The goal behind FDA regulation is consumer safety. In 2015, the FDA issued guidance for the mHealth industry16 and issued draft guidance for the wellness industry regarding low risk devices, which was finalized in 2016.17 These
guidance documents do not have the force of law, but they provide wellness professionals and organizations a window into how the FDA views certain health technologies in relation to the Food, Drug, and Cosmetic Act (“FDCA”). After briefly describing the FDCA as applied to medical devices, this article will summarize the current FDA guidance for mHealth and low risk wellness devices.

The FDCA and Regulation of Medical Devices

Congress created the FDA in 1906 to govern therapeutic drugs. At that time, medical devices were not thought to be appropriate candidates for federal regulation because very few products existed for prolonged application for the human body. The 1938 FDCA expanded the FDA’s authority to include the regulation of medical devices. However, the FDA did not have authority to require the manufacturer of any device to prove the safety, much less the effectiveness, of its product. With the introduction of highly sophisticated medical technologies in the 1960s, the FDA began to push for stronger regulatory authority over medical devices. After almost a decade of debate on the proper regulatory systems, in 1976 Congress amended the FDCA with the Medical Device Amendments (“MDA”). These amendments broadly defined a medical device as follows:

An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease . . . or intended to affect the structure or function of the body.

Thus, an important consideration of whether a device is subject to FDA medical device regulation is to determine the device’s “intended use.” To determine the intended use, the FDA looks at a product’s labeling claims, advertising matter, or oral or written statements by manufacturers or their representatives. Generally, products, including software, are considered medical devices if they are intended for a medical purpose. Thus, wellness companies that develop devices intended for medical purposes may fall within the ambit of FDA medical device regulation.

If a product is considered a medical device, the manufacturer must comply with certain FDA regulatory requirements. These requirements include:

• Establishment Registration – Manufacturers (both domestic and foreign) and initial distributors (importers) of medical devices must register their establishments with the FDA. All establishment registrations must be submitted electronically unless a waiver has been granted by the FDA. All registration information must be verified annually between October 1st and December 31st of each year. In addition to registration, foreign manufacturers must also designate a U.S. Agent. Most establishments are required to pay an establishment registration fee.

• Medical Device Listing – Manufacturers must list their devices with the FDA. Establishments required to list their devices include:
  1. manufacturers,
  2. contract manufacturers that commercially distribute the device,
  3. contract sterilizers that commercially distribute the device,
  4. repackagers and relabelers,
  5. specification developers,
  6. reprocessors of single-use devices,
  7. remanufacturers,
  8. manufacturers of accessories and components sold directly to the end user, and

• Premarket Notification 510(k), unless exempt, or Premarket Approval (“PMA”) – Compared to the 510(k) process, PMA is a much more rigorous process because the manufacturer of PMA devices must prove efficacy and safety by providing data showing the device’s performance in humans. The 510(k) process does not require human testing to prove efficacy and safety because these devices are considered to be at least as safe and effective as similar devices already on the market.

Devices that require the submission of a Premarket Notification 510(k) may not be commercially distributed until the FDA authorizes distribution through a letter of substantial equivalence. A 510(k) device must demonstrate that it is substantially equivalent to one legally in commercial distribution in the United States: (1) before May 28, 1976; or (2) to a device that has been determined by FDA to be substantially equivalent. There are three different classes of devices under FDA regulation, as discussed below. Most Class I devices and some Class II devices are exempt from the Premarket Notification 510(k) submission.

Products requiring PMAs are Class III devices, high risk devices that pose a significant risk of illness or injury, or devices found not substantially equivalent to Class I and II predicates through the 510(k) process. The PMA process is more involved and includes the submission of clinical data to support claims made for the device.

• Investigational Device Exemption (IDE) for clinical studies – An investigational device exemption (“IDE”) allows the investigational device to be used in a clinical study

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in order to collect safety and effectiveness data required to support a PMA application or a Premarket Notification 510(k) submission to the FDA. Clinical studies with devices of significant risk must be approved by the FDA and by an Institutional Review Board (“IRB”) before the study can begin. Studies with devices of nonsignificant risk must be approved by an IRB only before the study can begin.13

- **Quality System (“QS”)** regulation – The QS regulation includes requirements related to the methods used in and the facilities and controls used for the designing, purchasing, manufacturing, packaging, labeling, storing, installing and servicing of medical devices. Manufacturing facilities undergo FDA inspections to assure compliance with the QS requirements.14

- **Labeling requirements** – Labeling includes labels on the device as well as descriptive and informational literature that accompanies the device.15

- **Medical Device Reporting (“MDR”)** – Incidents in which a device may have caused or contributed to a death or serious injury must be reported to the FDA under the Medical Device Reporting program. Certain malfunctions must also be reported. The MDR regulation is a mechanism for the FDA and manufacturers to identify and monitor significant adverse events involving medical devices. The goals of the regulation are to detect and correct problems in a timely manner.16

As described earlier, the FDA regulates three different classes of medical devices.17 Under this classification system, the FDA determines the amount of pre-market and post-market regulation required by the FDCA.18 The higher the classification, the more scrutiny the device receives.19 The three classes of medical devices are as follows:

- **Class I devices** are regulated the least and generally do not require any pre-market review by the FDA. Examples of Class I devices include elastic bandages and examination gloves.20

- **Class II devices** have “moderate risk” and are subject to a relatively cursory premarket notification, known as a 510(k) notice, which the FDA generally accepts.21 In addition, Class II devices undergo special controls such as performance standards, post-market surveillance, patient registries, special labeling requirements, pre-market data requirements and guidelines.22 Examples of Class II devices include x-ray machines, powered wheelchairs and acupuncture needles.23

- **Class III devices** are high risk devices and generally require PMA.24 PMA is a complex and expensive process that obligates the manufacturer to submit clinical data proving the device’s safety and effectiveness.25 The approval process can take over five months, on average, even if a device is simply a newer version of an already approved device (i.e., a 510(k) clearance).26 Therapeutic drugs must go through a similar approval process.27 Examples of Class III devices include implantable pacemaker pulse generators and endoscopic implants.28

The FDCA also gives the FDA the authority to set good manufacturing practice requirements for medical devices, to ban worthless and dangerous products from the market, and to require notification, replacement or refund by makers of defective products.29

With regard to software, the FDA has long considered software products to meet the definition of a device when the software is intended for use in diagnosing and treating diseases and other conditions.30 Although the FDA views software products as within FDCA purview, the FDA announced that it would exercise “enforcement discretion” over many types of low-risk software, such as software that merely provides information.31 “Enforcement discretion” means that the FDCA applies to the device and the FDA has legal authority to enforce regulations, but it chooses not to enforce those regulations.32 The take-away regarding FDA regulation of devices is that if the device is intended to diagnose or treat a disease or condition, it is likely that it will be subject to FDA regulation.

### Guidance for Mobile Medical Apps and Low Risk Wellness Devices

The FDCA grants the FDA authority to issue regulations and allows interested parties to request a public hearing as part of the rulemaking process.33 The FDCA also includes residual rulemaking authority to address matters not specifically covered by the formal rulemaking provision.34 This enables the FDA to conduct notice-and-comment procedures for the promulgation of rules.35 This “informal” rulemaking procedure avoids the burdensome hearing procedure required with formal rulemaking.36 Yet even informal rulemaking has become lengthy and difficult for the FDA.37 As a result, the FDA has resorted to issuing “guidance,” offering the FDA a convenient short cut for communicating its expectations to regulated entities.38 The guidance process is not without critics, however. A primary criticism is that these informal announcements operate as de facto rules without the normal procedural safeguards that allow for public comment and review.39 Despite this criticism, the FDA has issued guidance documents for both mobile medical apps and low risk wellness devices.
Mobile Medical Apps Guidance

The FDA provided guidance relating to mobile medical applications on February 9, 2015.60 The guidance defines “mobile medical app” as a software application that can be run on a smart phone, tablet or other portable computer, or a web-based software platform tailored to a mobile platform but executed on a server that meets the definition of device in § 201(h) of the FDCA and either is intended: a) to be used as an accessory to a regulated medical device; or b) to transform a mobile platform into a regulated medical device.61 Generally, if a mobile app is intended for use in performing a medical device function (i.e., for diagnosis of disease or other conditions, or the cure, mitigation, treatment, or prevention of disease) it is a medical device, regardless of the platform on which it is run.62 Recall that the FDA looks at a product’s labeling claims, advertising materials or oral or written statements by manufacturers or their representatives to determine a device’s intended use.63

The key for wellness professionals and organizations is to determine whether a mobile app constitutes a mobile “medical” app or just a mobile app. If the latter, the FDA will exercise enforcement discretion, which as noted earlier means the FDA chooses not to enforce compliance of those apps under the FDCA.64 If the app is a mobile “medical” app, then the FDA will apply its regulatory oversight over those apps at one of the three classification levels discussed earlier.65 See Table 1 for examples of apps the FDA considers to be mobile “medical” apps subject to its oversight.66 Examples of mobile apps over which the FDA intends to exercise enforcement discretion because they are lower risk are listed in Table 2.67

Regardless of whether a medical device is subject to FDA enforcement authority or is one for which the FDA applies enforcement discretion, the FDA strongly recommends that manufacturers of all mobile apps that may meet the definition of a medical device follow the QS regulation in the design and development of those apps.68 This regulation includes good manufacturing practices.69 A partial list of these practices are:

1. Having a quality policy
2. Conducting quality audits
3. Having sufficient personnel with the necessary education, background, training and experience to ensure a quality device
4. Having design controls to ensure that specified design requirements are met
5. Having production and process controls
6. Having procedures to ensure devices are routinely calibrated, inspected, checked and maintained
7. Having procedures to handle products that do not conform to specified requirements
8. Creating and maintaining a device history record.70

In addition to mobile apps, wellness professionals and organizations may develop or encounter other products that the FDA considers to present

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<thead>
<tr>
<th>TYPE OF MOBILE MEDICAL APP</th>
<th>EXAMPLES</th>
<th>MUST COMPLY WITH:</th>
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<tr>
<td>Apps that transform the mobile platform into a regulated medical device by using attachments, display screens, or sensors or by including functionalities similar to those of currently regulated medical devices.</td>
<td>• Blood glucose strip reader attached to a mobile platform to function as glucose meter; • Attachment of electrocardiograph electrodes to mobile platform to measure, store, and display ECG signals; • Apps that use built-in accelerometer on a mobile platform to collect motion information for monitoring sleep apnea; • Apps that use sensors (internal and external) on a mobile platform for creating electronic stethoscope function; • Apps that display radiological images for diagnosis.</td>
<td>The device classification associated with the transformed platform.</td>
</tr>
<tr>
<td>Apps that become a regulated medical device (software) by performing patient-specific analysis and providing patient specific diagnosis or treatment recommendations.</td>
<td>• Apps that use patient-specific parameters and calculate dosage or create a dosage plan for radiation therapy; • Computer Aided Detection (“CAD”) software image processing software; • Radiation therapy treatment planning software.</td>
<td>The FDA encourages manufacturers of this type of app to contact the FDA to discuss what, if any, regulatory requirements may apply.</td>
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Table 1 – Mobile Medical Apps with FDA Regulatory Oversight

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Table 2 – Mobile Apps with FDA Enforcement Discretion

<table>
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<th>TYPE OF MOBILE APP</th>
<th>EXAMPLES</th>
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| Apps that provide or facilitate supplemental clinical care, by coaching or prompting, to help patients manage their health in their daily environment. | • Apps that coach patients with conditions such as cardiovascular disease, hypertension, diabetes or obesity, and promote strategies for maintaining a healthy weight, getting optimal nutrition, exercising, managing salt intake, or adhering to pre-determined medication dosing schedules by simple prompting.  
• Apps that use video and video games to motivate patients to do their physical therapy exercises at home.  
• Apps that provide periodic educational information, reminders, or motivational guidance to smokers trying to quit, patients recovering from addiction, or pregnant women.  
• Apps that prompt a user to enter which herb and drug they would like to take concurrently and provide information about whether interactions have been seen in the literature and a summary of what type of interaction was reported;  
• Apps that use patient characteristics such as age, sex, and behavioral risk factors to provide patient-specific screening, counseling and preventive recommendations from well-known and established authorities. |
| Apps that provide patients with simple tools to organize and track their health information. | Apps that provide simple tools for patients with specific conditions or chronic disease such as obesity, Anorexia, arthritis, diabetes, or heart disease to log, track or trend their events or measurements (e.g., blood pressure measurements, drug intake times, diet, daily routine or emotional state) and share this information with their healthcare provider as part of a disease management plan. |
| Apps that are specifically marketed to help patients document, show or communicate to providers potential medical conditions. | • Apps that serve as videoconferencing portals specifically intended for medical use and to enhance communications among patients, healthcare providers, and caregivers;  
• Apps specifically intended for medical uses that utilize a mobile device’s built-in camera or a connected camera for purposes of documenting or transmitting pictures (e.g., photos of a patient’s skin lesions or wounds) to supplement or augment what would otherwise be a verbal description in a consultation between or with a healthcare provider. |
| Apps that perform simple calculations routinely used in clinical practice.        | Medical calculators for:  
• Body Mass Index (“BMI”)  
• Total Body Water/Urea Volume of Distribution  
• Mean arterial pressure  
• Glasgow Coma Scale score  
• APGAR score  
• National Institutes of Health Stroke Scale  
• Delivery date estimator |
| Apps that meet the definition of Medical Device Data Systems.                     | • Apps intended to transfer, store, convert format, and display medical device data, without controlling or altering the functions or parameters of any connected medical device. These apps include those that are used as a secondary display to a regulated medical device when these apps are not intended to provide primary diagnosis, treatment decisions, or to be used in connection with active patient monitoring. |
“low risk” to consumer safety. Unlike mobile apps that the FDA still considers are medical devices (and either applies its enforcement authority or does not), the FDA concludes that this third category of mobile apps are not medical devices at all and therefore have no regulatory requirements under the FDCA.71 These include apps intended to provide access to e-copies of reference materials not meant for use in the diagnosis, treatment or prevention of disease, apps intended as medical training tools, apps for general patient education, apps that automate general healthcare office operations, and apps that are generic aids not specifically intended for medical purposes, such as an app that uses the mobile platform for note taking or as a magnifying glass.

Guidance for Low Risk Wellness Devices

The FDA released its final guidance regarding low risk wellness devices on July 29, 2016.73 According to the FDA, low risk products generally promote a healthy lifestyle and meet the following two factors: (1) are intended for only general wellness use; and (2) present a very low risk to users’ safety.74

Intended for General Wellness Only

The FDA defines a general wellness product as one that meets one of the following: (1) has an intended use that relates to maintaining or encouraging a general state of health or a healthy activity; or (2) an intended use claim that associates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions and where it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition.75

Importantly, the first category of general wellness product does not make any reference to diseases or conditions. To fall within this category, the general wellness product may relate to:

- Weight management
- Physical fitness, including products intended for recreational use
- Relaxation or stress management
- Mental acuity
- Self-esteem (e.g., devices with a cosmetic function that make claims related only to self-esteem)
- Sleep management
- Sexual function.76

In contrast, products that relate to the following would not qualify as general wellness products (and therefore could be subject to FDA regulation under one of the three class levels discussed earlier):

- The treatment or diagnosis of obesity
- The treatment of an eating disorder
- The treatment of anxiety
- A computer game that will diagnose or treat autism
- The treatment of muscle atrophy or erectile dysfunction
- The restoration of a structure or function impaired due to a disease (e.g., a claim that a prosthetic device enables amputees to play basketball).77

The second category of general wellness products is comprised of two subcategories: (1) intended uses to promote, track, and/or encourage choices, which, as part of a healthy lifestyle, may help to reduce the risk of certain chronic diseases or conditions; and (2) intended uses to promote, track and/or encourage choices which, as part of a healthy lifestyle, may help living well with certain chronic diseases or conditions.78 Both subcategories of disease-related wellness products should only make claims about healthy lifestyle choices reducing the risk of chronic disease or a medical condition if those claims are generally accepted and described in peer-reviewed scientific publications.79

For example, it is generally accepted that a healthy lifestyle reduces the risk of or helps better manage heart disease, high blood pressure and type 2 diabetes.80

Given the “first category” and “second category” descriptions above of general wellness products, it appears that wearable technology (e.g. Fitbit, Jawbone) devices that track data such as exercise and dietary behavior would be considered low risk wellness devices and therefore not subject to any FDA regulatory requirements. They also present a very low risk to the user’s safety, as described below. However, if this technology changes in the future (e.g., it becomes a medical device that is intended to diagnose and treat a disease), it would be subject to FDA regulations. Therefore, workplace wellness programs that provide wearable technology for their employees may not need to be concerned with these FDA regulations at the moment, but may need to comply with FDA requirements as technology changes and moves more into clinical applications. And of course, wellness programs that use information collecting devices must still address compliance with privacy, confidentiality, and security regulations.

Presents a Very Low Risk to User’s Safety

In addition to being intended for general wellness, in order for a product to qualify as a low risk wellness device the product must also not present inherent risks to a user’s safety.81 The FDA considers a product to present an inherent risk to a user’s safety if the product:

- Is invasive,
- Involves an intervention or technology that may pose a risk to a user’s safety if device controls are not applied, such as risks from lasers, radiation exposure, or implants,
- Raises novel questions of usability, or
- Raises questions of biocompatibility.82

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Examples of such products include:

• Sunlamp products promoted for tanning purposes (exposure to ultraviolet radiation creates an increased risk of skin cancer),

• Implants promoted for improved self-image or enhanced sexual function (creates an increased risk of rupture or adverse reaction to implant materials, as well as from the implantation procedure),

• A laser product that claims to improve confidence in a user’s appearance by rejuvenating the skin (laser technology presents risk of skin and eye burns and presents usability considerations that may be addressed with labeling and other device controls).83

Another way to determine whether a wellness device qualifies as low risk is to investigate whether the FDA already regulates products of the same type as the product in question.84 Wellness professionals and organizations may visit the FDA website85 to search for similar products that the FDA might already regulate. For example, a wellness organization may develop a glucose monitor for diabetic employees. Upon searching the FDA website, one discovers that the FDA regulates as a Class I device a “continuous glucose monitor retrospective data analysis software.”86 Thus, to the extent that the wellness organization's device is similar to the device already regulated by the FDA, the new device would not qualify as a low risk wellness device exempt from FDA regulation.

Thus, a product that qualifies as a low risk wellness device is not subject to FDA regulation. The FDA does not intend to examine these low risk products to determine whether they are “medical devices” subject to the FDCA or, if they are devices, whether they are in compliance with the FDCA.87 As of the date of this article, the author is not aware of any cases or other enforcement action raising the issue of FDA regulation of low-risk wellness devices. Moreover, the Cures Act clarifies that exempt from FDA regulation are any software functions intended “for maintaining or encouraging a healthy lifestyle” and is unrelated to the “diagnosis, cure, mitigation, prevention, or treatment of a disease or condition.”88

Putting it Together

Wellness professionals and organizations may wonder how the FDA Guidance for Mobile Apps and Guidance for Low Risk Wellness Devices relate. Mobile apps can be a type of low risk wellness device, as shown in the diagram in Figure 1.

So, a wellness professional or organization that uses a mobile app as part of a wellness program should first determine if it is a general wellness product not subject to FDA regulation.89 If it is determined that the mobile app does not qualify as a general wellness product, then the wellness professional or organization should consult the Mobile Medical Applications Guidance to determine whether the FDCA applies to the app.

Conclusion

The use of mHealth in health and wellness programs is evolving, as is the technology of mHealth and the law governing it. The increased reliance on mobile devices as a tool to foster health and reduce the cost of care will likely spur more interest in incorporating mHealth into wellness initiatives of all kinds. On the flip side, organizations that have made their mark in the wellness industry are looking to bring their expertise in health promotion and return on investment to the healthcare delivery space. Wellness organizations, employers who offer wellness programs, health-care systems, and attorneys need to keep an eye on this changing area of the law.

This article is adapted from the ABA Health Law Section’s new book, Rule the Rules of Workplace Wellness Programs. The book covers health and workplace wellness, with a focus on the legal and logistic aspects and helping guide the professionals developing legally healthy wellness programs in the workplace. For more information, go to:
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Ms. Zabawa is licensed to practice law in both Wisconsin and New York. She may be reached at bzabawa@wellnesslaw.com.

Endnotes


3. Id.

4. Id.; see also Daniel Cooper, These Companies think the future of wearables is wellness, not watches, Engadget (March 10, 2015), available at https://www.engadget.com/2015/03/10/the-future-of-wearables/.


6. John Carreyrou, supra note 5.

7. Id.


11. Id.


13. Id.

14. Id. at 1197.


16. FDA, Mobile Medical Applications Guidance for Industry and Food and Drug Administration Staff (February 9, 2015), available at http://www.fda.gov/downloads/MedicalDevices/.../UCM263366.pdf. This guidance superseded the guidance for mobile medical applications issued on September 25, 2013. The FDA recently noted that is assessing how to update this guidance in light of section 3060 of the 21st Century Cures Act (“Cures Act”), Pub. L 114-255 (December 13, 2016), which clarified that the definition of “device” excluded certain software functions, such as clinical decision support software and administrative support for a facility.


18. See e.g., FDA, Guidelines with Digital Health Content, (February 9, 2015), available at https://www.fda.gov/MedicalDevices/DigitalHealth/ucm362577.htm (noting that the FDA’s guidance documents do not establish legally enforceable responsibilities).


20. Id.

21. Id.

22. Id.

23. Id. at 1084-85.


25. Id. at 1086 (noting that the regulatory language for medical devices and drugs is identical, but that the level of regulation is much less strict for most devices).

26. Id.

27. The U.S. agent must either reside in the United States or maintain a place of business in the United States. The U.S. agent cannot use a post office box as an address. The U.S. agent cannot use just an answering service. The agent must be available to answer the phone or have an employee available to answer the phone during normal business hours. The responsibilities of the U.S. agent are limited and include:

• assisting the FDA in communications with the foreign establishment,

• responding to questions concerning the foreign establishment’s devices that are imported or offered for import into the United States,

• assisting the FDA in scheduling inspections of the foreign establishment, and

• if the FDA is unable to contact the foreign establishment directly or expeditiously, the FDA may provide information or documents to the U.S. agent, and such an action
shall be considered to be equivalent to providing the same information or documents to the foreign establishment.


29. Id.


31. U.S. Food and Drug Administration, Overview of Device Regulation, Fact Sheet, note 28, supra (citing 21 C.F.R. Part 807, Subpart E). The FDA may charge a fee for medical device Premarket Notification 510(k) reviews. A small business may pay a reduced fee. The application fee applies to Traditional, Abbreviated, and Special 510(k)s. The payment of a premarket review fee is not related in any way to the FDA’s final decision on a submission. Id.

32. Id. (citing 21 C.F.R. Part 814). Medical device user fees apply to original PMA and certain types of PMA supplements. Small businesses are eligible for reduced or waived fees. Id.

33. Id. (citing 21 C.F.R. Part 812). Under FDA regulations, an IRB is an appropriately constituted group that has been formally designated to review and monitor biomedical research involving human subjects. In accordance with FDA regulations, an IRB has the authority to approve, require modifications in (to secure approval), or disapprove research. This group review serves an important role in the protection of the rights, safety and welfare of human research subjects. U.S. Food & Drug Administration Fact Sheet, IDE Institutional Review Boards (IRB) (June 26, 2014), available at https://www.fda.gov/medicaldevices/device regulationandguidance/howtomarketyour device/investigationaldeviceexemptionid/ ucm046745.htm.


35. Id. (citing 21 C.F.R. Part 801).

36. Id. (citing 21 C.F.R. Part 803).

37. Stephen McInerney, note 19, supra, at 1073, 1086.

38. Id.


40. Id.


42. Id. at 1087, 1201.

43. McInerney, Can You Diagnose Me Now?, at 1087.

44. Id.

45. Id.


47. McInerney, Can You Diagnose Me Now? at 1087.

48. Id.


50. Id. at 1087-88.

51. Id. at 1088.

52. Id.


55. Noah, Governance by the Backdoor at 94-95. Id. at 95.

56. Id.

57. Id. at 97.

58. Id.

59. FDA, Mobile Medical Applications Guidance for Industry and Food and Drug Administration Staff (Feb. 9, 2015), note 16, supra.

60. Id. at 7.

61. Id. at 8.

62. Id.

63. Id. at 13.

64. Id. at 14-15.

65. Id. at 16-18; 23.

66. Id. at 13.

67. Id.

68. 21 C.F.R. Part 820.

69. FDA, Mobile Medical Applications Guidance for Industry and Food and Drug Administration Staff, at 20.

70. Id. at 20-22.

71. FDA, General Wellness: Policy for Low Risk Devices, Guidance for Industry and Food and Drug Administration Staff (July 29, 2016), available at http://www.fda.gov/downloads/medicaldevices/device regulationandguidance/guidancedocuments/ucm429674.pdf. The FDA is assessing how this Guidance may need to be updated in light of the clarifications in the Cures Act which exclude some software functions from the definition of device. See note 16, supra.

72. Id. at 1-2.

73. Id. at 3.

74. Id. at 3.

75. Id. at 4.

76. Id.

77. Id. at 4.

78. Id.

79. Id. at 5.

80. Id.

81. Id. at 6.


84. FDA, General Wellness: Policy for Low Risk Devices, Guidance for Industry and Food and Drug Administration Staff, note 73, supra, at 2.

85. Pub. L. 114-255, § 3060 (Dec. 13, 2016). As noted in note 16, supra, the Act also exempts from FDA regulation software functions intended for administrative support of a healthcare facility, such as financial, billing, scheduling, admissions, data analytics, laboratory workflow, population health management or inventory management, as well as certain electronic patient record software. Id.

86. The FDA’s 2016 general wellness guidance for industry and FDA staff, note 73, supra, contains a decision algorithm to determine whether a mobile app is a general wellness product. The FDA may update this algorithm in light of the Cures Act, which clarifies that certain software functions, such as some related to encouraging or maintaining a healthy lifestyle are exempt from such regulation.
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<td>December 5, 2017</td>
<td>Known Unknowns: Ethics Challenges in Advising Healthcare Clients When Uncertainties are Certain</td>
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<td>December 7, 2017</td>
<td>Fined by the OCR for HIPAA Problems Yet? HIPAA, Privacy &amp; Security Fundamentals CLE Webinar</td>
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<td>December 14, 2017</td>
<td>What Should be on Your Anti-Kickback Statute Radar: A Master Class on Enforcement &amp; Guidance Trends CLE Webinar</td>
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<td>January 16, 2018</td>
<td>Medicaid Coverage, Cost Sharing, and Reimbursement for Adult Vaccinations Free Member Benefit Webinar</td>
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<td>January 18, 2018</td>
<td>Anatomy of a Business Associate Agreement CLE Webinar</td>
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<td>January 31 – February 6, 2018</td>
<td>ABA Midyear Meeting Vancouver, BC</td>
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<td>February 6, 2018</td>
<td>Transitioning from Gov’t to Private Sector CLE Webinar</td>
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<td>February 15, 2018</td>
<td>Medicare &amp; Medicaid Fundamentals CLE Webinar</td>
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<td>February 21-24, 2018</td>
<td>Emerging Issues in Healthcare Law In-person</td>
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<td>March 22, 2018</td>
<td>Medical Malpractice CLE Webinar</td>
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<td>April 5, 2018</td>
<td>Fundamentals of Healthcare Compliance CLE Webinar</td>
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<td>April 19, 2018</td>
<td>TeleHealth Master Class CLE Webinar</td>
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<td>May 17-18, 2018</td>
<td>Antitrust in Healthcare Conference Arlington, VA</td>
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<td>June 21, 2018</td>
<td>Mediation CLE Webinar</td>
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<td>July 26, 2018</td>
<td>Drug Approval Master Class CLE Webinar</td>
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<td>August 23, 2018</td>
<td>HIPAA Breach CLE Webinar</td>
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