A Marketing Compliance Primer for Healthcare Providers

Anna M. Grizzle* & Lori S. Richardson Pelliccioni

I. Introduction

In an increasingly competitive marketplace, healthcare providers are turning to creative advertising and communications strategies to differentiate themselves from their competitors. Whether undertaken by or behalf of (or directed toward) healthcare providers, marketing activities in the healthcare industry are subject to a complex web of laws and regulations, and non-compliance can lead to severe penalties.¹ What is common practice in other industries may pose significant risks in the healthcare industry.

Healthcare providers face special challenges in ensuring that their marketing efforts comply with applicable fraud and abuse laws, perhaps the most important of which is the federal anti-kickback statute (the “Anti-Kickback Statute”). In addition, healthcare providers must consider the potential application of information privacy laws and telecommunications laws. Suppliers of durable medical equipment, prosthetics, orthotics, and supplies ("DMEPOS") are subject to additional requirements concerning direct patient contact or telemarketing activities. In an environment in which combatting healthcare fraud and abuse is a national priority,²

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¹ This paper is intended to provide general background information on some of the legal constraints associated with marketing activities undertaken by or on behalf of healthcare providers and, to a lesser extent, durable medical equipment suppliers. It is not intended to review the legal considerations associated with marketing activities directed toward healthcare providers nor is it intended to review concerns associated with the promotion of prescription drugs for unapproved or off-label uses. It is worth noting that the latter issue has been the subject of considerable enforcement activity and has resulted in significant liability for pharmaceutical manufacturers, including a $3 billion settlement entered into by GlaxoSmithKline and the Department of Justice in July 2012.

² See, e.g., Comments of Attorney General Eric Holder, United States Department of Justice, “Attorney General Eric Holder Speaks at Health Care Fraud and Abuse Control Program Report Press Conference” (Feb. 14, 2012), available at http://www.justice.gov/iso/opa/ag/speeches/2012/ag-speech-120214.html (noting that the Health Care Fraud Prevention and Enforcement Action Team or “HEAT” initiative has “elevated our nation’s fight against both civil and criminal health-care fraud” and that the initiative is a “Cabinet-level priority”).
healthcare providers must carefully navigate these limitations when considering any effort that may be construed as marketing.

This paper is intended to provide a broad overview of the legal considerations associated with marketing activities by healthcare providers in four major areas. First, the paper provides an overview of the major federal healthcare laws and regulations impacting healthcare providers’ marketing efforts, including the Anti-Kickback Statute, the physician self-referral prohibition (the “Stark Law”), the Civil Money Penalty Law (the “CMP Law”), and the Health Insurance Portability and Accountability Act (“HIPAA”), as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH”). Second, the paper addresses the potential impact of federal telecommunications laws and regulations on healthcare providers’ marketing activities, with a particular focus on telemarketing. Third, specific limitations placed on marketing activities undertaken by DMEPOS suppliers is reviewed. Fourth, practical guidance is offered as to how healthcare providers and suppliers can structure their marketing efforts in a manner that complies with the complex legal framework governing such activities.

II. Federal Healthcare Laws and Regulations Impacting Provider Marketing

A. The Anti-Kickback Statute

Enacted in 1972 and expanded extensively over the past 40 years, the Anti-Kickback Statute seeks to prevent the overall increase of healthcare costs to federal healthcare programs due to referral payments for unnecessary services or items. The Anti-Kickback Statute establishes criminal and civil prohibitions against knowingly and willfully offering, paying, soliciting, or receiving any remuneration directly or indirectly, in cash or in kind, to induce or

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3 While this paper is intended to provide general background information on some of the federal laws that may impact healthcare providers’ marketing activities, it is not intended to be comprehensive in scope. In particular, this paper does not review state laws that may be implicated by marketing activities (e.g., patient solicitation laws, state anti-fraud and anti-kickback laws, consumer protection laws). All such laws should be carefully considered in the analysis of a marketing arrangement.
reward (1) the referring of an individual for the furnishing or arranging for the furnishing of items or services reimbursable by a federal healthcare program or (2) the purchasing, leasing, or ordering, or the arranging for or recommending the purchasing, leasing, or ordering of items or services reimbursable by a federal healthcare program. Because payment by a healthcare provider to a marketer may be seen as an inducement to cause the marketer to arrange for or recommend the purchase of services from the healthcare provider, most third-party marketing arrangements have the potential to implicate the statute. In addition, the Anti-Kickback Statute’s prohibition of the provision of remuneration, a broadly defined term, to induce a person to purchase services reimbursable by a federal healthcare program may be implicated by direct marketing activities undertaken by healthcare providers.

An individual need not actually make a prohibited referral for the Anti-Kickback Statute to be implicated. Simply providing a physician or other healthcare provider with the opportunity to earn money by referring patients for a particular service or to use a particular product that may be reimbursed by a federal healthcare program may be sufficient to violate the statute. Furthermore, the Anti-Kickback Statute has long been interpreted to cover any arrangement where one purpose of the remuneration was to induce or reward referrals. In 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education

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4 42 U.S.C. § 1320a-7b(b). Although the terms “recommending” and “arranging” are used in the Anti-Kickback Statute, they are not defined in the statute or its implementing regulations.

5 The term “remuneration” is not defined by the Anti-Kickback Statute or its implementing regulations; however, the term has been interpreted to include any type of cash or in-kind benefit that can be assigned a monetary value (e.g., interest-free loans, supplies, equipment). See, e.g., United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985).

6 See United States v. Bay State Ambulance & Hosp. Rental Serv., Inc., 874 F.2d 20, 29, 34 (1st Cir. 1989) (noting that “the government need not show that one accepting a payment for an illegal purpose actually carried through on his promise”).

7 See, e.g., United States v. Borrasi, 639 F.3d 774 (7th Cir. 2011); United States v. McClatchey, 217 F.3d 823 (10th Cir. 2000); United States v. Davis, 132 F.3d 1092 (5th Cir. 1998); United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985).

Reconciliation Act of 2010 (collectively, the “ACA”), revised the intent requirement such that actual knowledge of or specific intent to violate the Anti-Kickback Statute is not required. Specifically, “a person need not have actual knowledge of [the Anti-Kickback Statute] or specific intent to commit a violation” in order to violate the statute.\(^9\) Merely the intent to induce the referral or purchase of items or services for which payment may be made in whole or in part by a federal healthcare program is sufficient.

Violation of the Anti-Kickback Statute constitutes a felony punishable by a criminal fine of up to $25,000 for each violation, imprisonment up to five years, or both. Violations may also result in civil money penalties of up to $50,000 per violation, damages of up to three times the total amount of the remuneration, and/or exclusion from participation in federal healthcare programs. In addition, the ACA provides that the submission of a claim for services or items generated in violation of the Anti-Kickback Statute constitutes a false or fraudulent claim and may therefore be subject to additional penalties under the federal False Claims Act.\(^11\)

The United States Department of Health and Human Services (“HHS”) Office of Inspector General (“OIG”) is tasked with protecting the integrity of Medicare, Medicaid, and other HHS programs, and has offered a great deal of interpretive guidance concerning marketing activities in the context of the Anti-Kickback Statute. The OIG has long observed the potential application of the Anti-Kickback Statute to marketing activities, noting:

The [Anti-Kickback Statute] on its face prohibits the offering or acceptance of remuneration, \textit{inter alia}, for the purposes of “arranging for or recommending the purchasing, leasing, or ordering of any […] service or item” payable under Medicare or Medicaid. Thus, we believe that many marketing and advertising activities may involve at least technical violations of the statute. We, of course, recognize that many of these advertising and marketing activities do not warrant prosecution in part because (1) they are passive in nature, \textit{i.e.}, the activities do not

\(^10\) 42 U.S.C. §1320a-7b(h), \textit{added by} the ACA, §6402(f)(2).
\(^11\) 42 U.S.C. §1320a-7b(g), \textit{added by} the ACA, §6402(f)(1).
involves direct contact with program beneficiaries, or (2) the individual or entity involved in these promotions is not involved in the delivery of health care. Such individuals are not in a position of public trust in the same manner as physicians or other health care professionals who recommend or order products and services for their patients.12

The OIG has addressed the problems presented by marketing and marketing-related activities in several advisory opinions.13 A review of these advisory opinions points to the following, non-exhaustive list of suspect factors:

(1) success fees, compensation based on a percentage of revenue, or compensation that reflects the generation of new business;14

(2) marketing by healthcare providers and suppliers (particularly “white coat” marketing by healthcare professionals) because they are in a position of trust and may exert undue influence.15

13 See OIG Adv. Op. No. 10-23 (Oct. 28, 2010) (marketing fees paid on the basis of successful orders for items or services are inherently subject to abuse because they are linked to business generated by the marketer); OIG Adv. Op. No. 08-19 (Oct. 29, 2008) (despite pay-per-call advertising structure, the OIG would not impose sanctions because the advertiser is not a healthcare provider or supplier, nor is it affiliated with the healthcare industry, the arrangement will not target federal healthcare program beneficiaries, and the payment structure does not depend upon whether the potential patient decides to become a patient of a chiropractor subscriber, and patients are not steered to particular chiropractors); OIG Adv. Op. No. 99-10 (Oct. 25, 1999) (OIG would not sanction a company for a corporate sponsorship program involving charitable donations in exchange for the exclusive use of a charity’s proprietary logos in promotional materials); OIG Adv. Op. No. 99-8 (Jul. 6, 1999) (OIG would not sanction a retail shoe department for in-store advertising and awareness campaigns regarding, and the provision of, a podiatrist to provide free foot exams to customers given low risk of abuse, i.e., retail company is not a healthcare provider in a position of influence, etc.); OIG Adv. Op. No. 99-3 (Mar. 16, 1999) (OIG would not sanction a Medicare skilled nursing facility regarding an arrangement involving independent contractor sales commission (20% of collections) for selling therapeutic mattresses and related-items to the facility because mattresses are not separately billed to Medicare, there was no risk of swapping); OIG Adv. Op. No. 98-10 (Aug. 31, 1998) (OIG would not sanction a manufacturer for use of an independent contractor sales agent on a commission basis to market and negotiate contracts with hospitals and group purchasing organizations, i.e. sophisticated purchasers, where the products were not separately reimbursable outside the hospitals’ payment); OIG Adv. Op. No. 98-4 (Apr. 15, 1998) (finding a percentage-based management arrangement problematic and potentially constituting a technical violation of the statute because the management company would have been performing marketing and billing services without sufficient safeguards to prevent fraud or abuse).
14 See also Medical Development Network, Inc., v. Professional Respiratory Care/Home Medical Equipment Services, Inc., 673 So.2d 565, 567 (Fla. App. 1996) (holding that an arrangement whereby an independent contractor is paid a percentage of the sales it generates for a durable medical equipment company violated the Anti-Kickback Statute and, therefore, the public relations agreement was unenforceable); Zimmer, Inc. v. Nu Tech Med., Inc., 54 F.Supp.2d 850 (N.D. Ill. 1999) (holding an agreement whereby an orthopedic soft goods manufacturer agreed to pay an independent contractor DME supplier a percentage of revenues of goods sold violated the Anti-Kickback Statute and giving considerable weight to the OIG’s rationale in Adv. Op. No. 98-1); but see United States v. Miles, 360 F.3d 472, 480 (5th Cir. 2004) (reversing Anti-Kickback Statute convictions for entering into a sales arrangement whereby a third party delivered promotional materials to area physicians and received $300 per patient that became a client of the home health company because the sales agents had no role in deciding to send patients).
(3) direct billing of a federal healthcare program by the seller for the item or service sold by the sales agent;

(4) direct contact between the sales agent and physician in a position to order items or services that are then paid for by a federal healthcare program;

(5) direct contact between the sales agent and federal healthcare program beneficiaries;

(6) marketing of items or services that are separately reimbursable by a federal healthcare program (e.g., items or services not included in a bundled or composite rate), whether on the basis of charges or costs\(^\text{16}\); and

(7) the degree to which the marketing activities may be coercive, or perceived to be coercive.

The list is not exhaustive and the OIG has indicated that the absence of any one factor does not mean that a sales arrangement is permissible under the Anti-Kickback Statute. In general, the more factors that are present, the greater the level of scrutiny an arrangement will receive.\(^\text{17}\)

The OIG has indicated that it will apply additional scrutiny where items or services are recommended, either expressly or implicitly, by healthcare professionals through “white coat” marketing and direct contact with beneficiaries and nursing facilities:

Marketing by physicians or other health care professionals – sometimes referred to as “white coat” marketing – is subject to closer scrutiny, since health care providers are in a position of trust and may exert undue influence when recommending health-care related items or services, particularly to their own patients. Patients typically believe that their health care providers furnish and recommend products or services that are in the patients’ best medical interests.

\(^{15}\) OIG Advisory Opinion No. 08-19, \textit{supra} note 7 (stating that marketing by healthcare providers and suppliers (particularly “white coat” marketing by healthcare professionals, such as physicians) is subject to closer scrutiny, since healthcare providers and suppliers are in a position of trust and may exert undue influence when recommending health-care related items or services, particularly to their own patients); OIG Adv. Op. No. 02-12 (Aug. 21, 2002) (noting that marketing by physicians or other healthcare professionals is particularly suspect given their influence over patients who trust their recommendations); \textit{see also} OIG Adv. Op. No. 99-12 (Nov. 23, 1999); OIG Adv. Op. No. 99-3, \textit{supra} note 7; Draft OIG Compliance Program Guidance for Pharmaceutical Manufacturers. 67 Fed. Reg. 62057, 62062 (Oct. 3, 2002); OIG Compliance Guidance for Pharmaceutical Manufacturers. 68 Fed. Reg. 23731 (May 5, 2003) regarding consulting and other arrangements with physicians.


One of the purposes of the Anti-Kickback Statute is to help ensure that the exercise of independent medical judgment is not corrupted by financial considerations.\(^{18}\)

In a recent Advisory Opinion, the OIG stated that it would not sanction the operator of a website that enabled “white coat” marketing by healthcare providers via purchased advertising space on a website through which providers could post coupons for healthcare services and items that may be paid for by federal healthcare programs.\(^{19}\) The OIG found that the operation of the website posed a low risk of fraud and abuse, in part, because the operator was not a healthcare provider or supplier but merely an independent conduit for advertising. However, the opinion noted that if the website were operated by a healthcare provider or supplier, the operation would be more suspect and scrutinized more closely.

Beyond marketing, the OIG has stated the following regarding consulting services performed by healthcare professionals for the pharmaceutical industry:

Pharmaceutical manufacturers frequently engage physicians and other health care professionals to act as “consultants,” “advisors,” or “researchers” in connection with various types of marketing and research activities. For instance, pharmaceutical manufacturers may engage physicians to perform research, data collection, and consulting services, to serve on advisory boards, to participate in focus groups, or to speak at meetings. While there may be legitimate purposes to these arrangements, they pose a substantial risk of fraud and abuse; without appropriate safeguards, they can result in payments for referrals.

Pharmaceutical manufacturers should ensure that they (and their sales agents) compensate health care professionals only for providing actual, reasonable, and necessary services and that the arrangements are not merely token arrangements created to disguise otherwise improper payments. Moreover, payments should be fair market value for the services rendered, and manufacturers should take steps to ensure appropriate documentation of the fair market value determination, as well as the performance of the services. Whenever possible, the OIG recommends that consulting and advisory arrangements be structured to fit in the personal services safe harbor.\(^{20}\)

\(^{20}\) Draft OIG Compliance Program, \textit{supra} note 9 at 62062; \textit{see also} OIG Compliance Guidance, \textit{supra} note 9.
Whether engaging in marketing or consulting services, physicians should endeavor to tailor any such arrangement to the exact requirements of a safe harbor.

1. **The Availability of Safe Harbor Protection**

The Anti-Kickback Statute provides several safe harbors that may protect remuneration that could otherwise be considered suspect. Safe harbors are intended to provide some comfort to providers and suppliers that proposed arrangements may be immune from prosecution under the statute. While compliance with a safe harbor is not mandatory, such compliance creates a presumption that the parties are meeting the statute’s statutory requirements. However, failure to satisfy a safe harbor does not conclusively establish that the arrangement violates the statute.

The most frequently used safe harbor in the context of commission-based compensation is the employment safe harbor, which allows employers to compensate in any manner an employee who has a *bona fide* employment relationship with the employer for the provision of services or items covered by a federal healthcare program. If an arrangement involves contracting with a third party for the marketing, sales and distribution of certain products, the employment safe harbor will not apply. In fact, in its initial proposed rule and in response to commenters’ suggestions that the employment exception be extended to independent contractors paid on a commission basis, the OIG declined to do so, elaborating:

In response to the October 21, 1987 request for comments, many commenters suggested that we broaden the [employment] exemption to apply to independent contractors paid on a commission basis. We have declined to adopt this approach because we are aware of many examples of abusive practices by sales personnel who are paid as independent contractors and who are not under appropriate supervision. We believe that if individuals and entities desire to pay a salesperson on the basis of the amount of business they generate, then to be exempt from civil or criminal prosecution, they should make these salespersons employees where they can and should exert appropriate supervision for the individual’s acts.

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Another potentially applicable safe harbor is the personal services and management contracts safe harbor. Indeed, the OIG has indicated that “many advertising and marketing activities warrant safe harbor protection under the personal services and management contracts safe harbor.”\(^\text{23}\) This safe harbor requires, among other things, a signed written agreement covering all services in which the aggregate compensation is set in advance, is consistent with fair market value and does not take into account the volume or value of referrals or business generated.\(^\text{24}\) A commission-based compensation arrangement would not qualify as “set in advance” and likely varies with the volume or value of business generated (\textit{i.e.}, sales). Moreover, the safe harbor requires the agreement specify the exact schedule of part-time or sporadic services, including intervals, length of time and the charge for each interval.\(^\text{25}\) Often parties find it impractical to specify an exact schedule of services for an entire year.\(^\text{26}\) Based on the foregoing, it is unlikely a commission-based compensation structure will qualify for safe harbor protection.


\(^{24}\) The personal services and management contracts safe harbor requires all of the following elements be met: (1) The agreement is set out in writing and signed by the parties; (2) The agreement covers all of the services the agent provides to the principal for the term of the agreement and specifies the services to be provided by the agent; (3) If the agreement is intended to provide for the services of the agent on a periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals; (4) The term of the agreement is for not less than one year; (5) The aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs; (6) The services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law; and (7) The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services. 42 C.F.R. §1001.952(d).

\(^{25}\) Id.

\(^{26}\) The OIG has recognized that healthcare providers, for various reasons, may be unable to specify the timing or duration of business arrangements, or the precise compensation involved but believes that both the “aggregate” and the “specific schedule of intervals” requirements are appropriate for purposes of granting protection from prosecution. See 64 Fed. Reg. 63518, 63526 (Nov. 19, 1999); 56 Fed. Reg. 35952 (Jul. 29, 1991). Several OIG Advisory Opinions also indicate a precise schedule and payment for those intervals is required. See e.g., OIG Adv. Op. No. 98-1, supra note 7 (the provision of training services for a flat fee did not meet the personal services and management contracts safe harbor because the safe harbor requires that for periodic, sporadic or part-time services, the schedule and precise length of the intervals for the performance of the services be set in advance).
An overarching issue in any Anti-Kickback Statute analysis is whether the arrangement was developed based on a legitimate and commercially reasonable business purpose. The OIG will generally look beyond a physical agreement to determine whether an arrangement makes commercial business sense and is not actually a kickback in disguise. For example, in Advisory Opinion No. 99-1, in addition to the marketing services at issue, the marketing company proposed to provide the orthopedic manufacturer 100 days of marketing training for $1000 per day, or $100,000 total. Since the schedule of training services could not be determined in advance, this portion of the arrangement did not meet the personal services and management contracts safe harbor. In evaluating compliance with the Anti-Kickback Statute, the OIG indicated the issue is whether the aggregate contractual amount ($100,000) represents fair market value for the training services. In addition, the OIG questioned the business purpose and commercial reasonableness of marketing training for the manufacturer’s personnel given that the manufacturer had contracted with the marketing company to perform its primary marketing services. The OIG pondered whether the training fees may represent disguised compensation for the marketing company’s activities that generate business.

Additionally, the OIG has identified manufacturer payments to providers for research services as an “area of potential risk” in the context of pharmaceuticals:

Payments for research services should be fair market value for legitimate, reasonable, and necessary services. Research contracts that originate through the sales or marketing functions – or that are offered to physicians [or other health care professionals] in connection with sales contracts – are particularly suspect. Indicia of questionable research include, for example, research initiated or directed by marketers or sales agents; research that is not transmitted to, or reviewed by, a manufacturer’s science component; research that is unnecessarily duplicative or is not needed by the manufacturer for any purpose other than the generation of business; and post-market research used as a pretense to promote product.27

27 OIG Compliance Guidance, supra note 9, at 23738; see also AdvaMed Code of Ethics on Interactions with Health Care Professionals, FAQ 35 (Jul. 1, 2009) (“A “legitimate need” to engage a health care professional as a consultant
With respect to such arrangements, a government regulator scrutinizing the arrangement would likely want to know the parties’ business rationale for entering the arrangement. For instance, what cost savings are providers able to offer the manufacturers that prompt them to enter into the arrangement with the providers rather than hiring their own medical professionals to perform the same function? How is any data gathered by the providers going to be used? Is the compensation paid to the providers in exchange for providing the consulting services sufficient even absent the opportunity to generate business for the provider or provider’s employer? Providers and manufacturers should ensure that their rationale is thoughtful, thorough and does not include any intent to inappropriately induce the purchase of items or services reimbursable by federal or state healthcare programs. However, under the Anti-Kickback Statute, neither a legitimate purpose for an arrangement, nor a fair market value payment, will necessarily protect remuneration if there is also an illegal purpose, such as the purposeful inducement of business.

2. **Applicable Case Law**

Several cases have addressed marketing arrangements and, in particular, the applicability of the Anti-Kickback Statute or a similar state law. While the arrangements at issue in these cases generally involve marketing activities undertaken on behalf of medical equipment suppliers (often directed to physicians), the decisions provide useful background in understanding how the Anti-Kickback Statute (and similar state laws) may be applied to marketing activities. In *People v. Palma*, the California Court of Appeals upheld the conviction “arises when a company requires the services of a health care professional in order to achieve a proper business objective. . . However, engaging a health care professional for the purpose of generating business directly from such health care professional (or a health care provider that is affiliated with the health care professional) is not a proper business objective. Thus, there is a legitimate business need to engage a health care professional only if the arrangement would have been entered into absent an opportunity to generate business directly from the health care professional. Further, the level of consulting services should not exceed the amount that is reasonably necessary to achieve a Company’s proper business objective.”
of an independent contractor sales agent of violating the California anti-kickback law for selling incontinence supplies to nursing homes.\(^{28}\) The sales agent was paid by the incontinence supply company per submitted stickers from Medi-Cal, California’s Medicaid program (i.e., $100 for those who were not incontinent and $120 for those who were) from 1989 to 1990. The Medi-Cal stickers were included on Medi-Cal beneficiaries’ identification cards. The stickers were intended to be torn off by providers and kept for their records to show that they were providing services to someone in the Medi-Cal program. In addition, the sales agent entered into an arrangement with an individual associated with a number of board-and-care homes whereby the sales agent would pay the individual $40 per Medi-Cal beneficiary sticker. The court held that the payments received by the sales agent constituted a kickback under California’s Medi-Cal kickback law, which is similar to the federal law.\(^{29}\)

Nursing Home Consultants, Inc. (“NHC”) v. Quantum Health Services, Inc. (“Quantum”) involved a marketing agreement between Quantum, a company that supplied medical equipment and supplies to nursing homes, and NHC, a marketing company that acted as the intermediary between nursing homes residents and certain medical suppliers.\(^{30}\) Pursuant to the marketing agreement, Quantum engaged NHC to broaden its sales base in certain geographic areas by identifying Medicare recipients who needed Quantum’s medical supplies. NHC would put those individuals in contact with Quantum and Quantum would sell products directly to the nursing home on behalf of its residents. NHC had no part in the actual sales of medical supplies to nursing home residents and was prohibited from providing any assistance to nursing home residents in connection with placing orders. NHC was compensated based upon the number of


\(^{29}\) See also United States v. Polin, 194 F.3d 863 (7th Cir. 1999)(convicting a nurse and physician who paid $50 for each Medicare patient referral to their cardiac monitoring company to a pacemaker sales representative who interacted often with the physician and was often tasked with contacting an outside monitoring company).

units Quantum sold to the nursing home residents such that “the more residents NHC referred to Quantum, the more money NHC made.” Ultimately, the court held the contract was not enforceable because it violated the Anti-Kickback Statute and, as a result, NHC could not recover for a breach of contract. The court found that NHC’s compensation was “directly pegged to the number of sales generated on behalf of Quantum” and based on depositions that the parties had been advised that the payment structure might be illegal.

In *Medical Development Network, Inc.* (“MDN”) v. *Professional Respiratory Care/Home Medical Equipment Services* (“PRC”), a Florida appellate court found a “public relations agreement” between the two parties to be void and unenforceable for violating the Anti-Kickback Statute. Under the agreement, MDN was paid a percentage of all business developed by MDN’s marketing of PRC’s products to clients, which included physicians, nursing homes, retirement homes and individual patients. MDN would contact the clients and promote PRC’s product. Thereafter, nursing homes would contact PRC directly to order equipment. Physicians would refer patients to PRC for lease or sale of medical equipment. In defending a breach of contract allegation, PRC alleged the contract was illegal and thus, unenforceable. On appeal, the court pointed to the OIG’s commentary in its 1989 proposed rule cited above in concluding that an arrangement whereby MDN received a percentage of the sales generated violated the Anti-Kickback Statute. Although the opinion is short and relatively vague on the facts, this case could be read broadly to stand for the proposition that marketing activities by independent contractors may be prohibited unless the personal services and management contracts safe harbor

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31 Id. at 839.
32 Id. at 844.
33 Medical Development Network, supra note 8.
34 Id; see also People v. Duz-Mor Diagnostic Laboratory, Inc., 80 Cal.Rptr.2d 419 (Cal.App.4th 1998) (interpreting California’s Medi-Cal Anti-Kickback Statute to prohibit the payment of a commission to someone who arranges, through marketing activities, for services to be furnished to Medi-Cal beneficiaries).
is met. On the other hand, PRC was directly billing the Medicare program for at least some of the products at issue. Thus, the decision-makers’ (i.e., patient, physician, nursing home) profits were not impacted by the cost of the product in the same way that a hospital bears the cost of surgical equipment.

Similarly in *Zimmer, Inc. v. Nu Tech Med., Inc.*, another independent contractor arrangement with commission-based compensation was found to be unenforceable because it violated the Anti-Kickback Statute. *Zimmer, Inc.* (“Zimmer”), a major manufacturer of orthopedic products and a subsidiary of Bristol-Myers Squibb, had entered into an independent contractor agreement with Nu Tech Med., Inc. (“Nu Tech”), a supplier of medical items, for the distribution and billing of Zimmer products.  

Under the arrangement, Zimmer agreed to consign a reasonable quantity of Zimmer soft goods products to Nu Tech for the purposes of stocking the shelves of referring physician offices. Nu Tech agreed to bill patients or its contracted insurance companies for the Zimmer products and forward the reimbursement less Nu Tech’s fees within 30 days of receiving the reimbursement. Nu Tech’s fees varied from 20% of receivables to 25% of receivables, depending on the total receivables (i.e., if receivables were less than $2 million, the Nu Tech fee was 25%, if receivables were between $2.1 and 4 million, the Nu Tech fee was 22%, etc.). The arrangement also involved Nu Tech providing consulting services, which entailed 100 days of sales training services to Zimmer for $1,000 per day, 60% of which was to be paid within 30 days of the agreement’s execution. After failing to pay the $60,000 for the consulting services after execution, a dispute between the parties arose and Zimmer questioned the legality of the agreement. Zimmer suggested the parties jointly submit a request for an OIG opinion, which Zimmer did on its own on December 18, 1997.

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35 *Zimmer, supra* note 8.
The resulting advisory opinion, OIG Advisory Opinion No. 98-1, labeled the arrangement’s percentage compensation mechanism as “problematic” and explained “percentage based compensation arrangements are potentially abusive […] because they provide financial incentives that may encourage overutilization of times and services and may increase program costs.”

The OIG highlighted the following:

1. **The Arrangement includes significant financial incentives that increase the risk of abusive marketing and billing practices.** The percentage amount of [Nu Tech’s] compensation is a factor in evaluating the Arrangement’s financial incentives. Moreover, the compensation is based on a percentage of the volume or value of business generated between the parties. Whereas [Zimmer] is not a Medicare supplier, [Nu Tech] will be a supplier and will actually bill the Federal health care programs. The “Medicare Prices” shown on the [Nu Tech] Contract Price List are in many cases substantially in excess of [Zimmer]’s list prices. To the extent that revenues under the Arrangement exceed -- in some instances by substantial amounts -- the revenues derived from prices currently charged by [Zimmer] to its list price purchasers, both [Zimmer] and [Nu Tech] stand to profit substantially.

2. **[Nu Tech] will have opportunities to unduly influence referral sources and patients.** The Arrangement involves active marketing, including direct contacts, by [Nu Tech] and [Zimmer] to physicians who order and dispense orthotic products. In addition, the Arrangement provides [Nu Tech] with opportunities to market directly to Medicare patients.

3. **The Arrangement contains no safeguards against fraud and abuse.** The Arrangement is particularly susceptible to abusive practices because the orthotic products at issue are paid for by third-party payers and patients, including the government, instead of by the physicians who order and dispense them.

In addition, the OIG noted that although they had received no information indicating any improper payments from Nu Tech to physicians to induce them to order Zimmer products, the arrangement contains “no apparent safeguards against such payments.” In concluding that the contract was unenforceable due to illegality, the court gave the advisory opinion considerable

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37 Id.
weight and rejected Nu Tech’s attempts to point out shortcomings in the opinion and differentiate some of the other cases referenced above. The court stated that:

Inclusion of the percentage-based compensation scheme appears to be sufficient to justify the conclusion that the parties' actions under the Agreement could be motivated by their desire and ability to increase sales of Zimmer products that might be paid for by federal or state health care programs. Regardless of which party was to be responsible for the marketing of the Zimmer products, the end result would be the same: the more products sold, the more money the parties would make.38

The Zimmer case and OIG Advisory Opinion No. 98-1 indicate that the Anti-Kickback Statute applies to manufacturer—distributor relationships, even if the manufacturer does not deal directly with the Medicare program.

Conversely in United States v. Miles,39 the Fifth Circuit reversed the Anti-Kickback Statute convictions of two individuals associated with Affiliated Professional Home Health (“APRO”), a home health company, after determining that a third party, Premier Public Relations (“Premier”), hired a sales agent to deliver promotional materials (i.e., written materials describing the home health agency’s services and an occasional tray of cookies) to area physician offices in exchange for $300 per patient that became a client of the home health company. The facts of the case demonstrated fraudulent activity, such as including the expenses of home renovations of the owners in APRO’s expenses. However, even in a case with some clear indications that the individuals were taking advantage of the federal healthcare program, the Miles court reversed the Anti-Kickback Statute convictions. The Miles court reasoned that Premier never actually “referred” anyone to the company. Rather, “after a doctor had decided to send a patient to APRO, the doctor’s office contacted Premier, which then supplied the necessary billing information to APRO and collected payment. There was no evidence that Premier had

38 Zimmer, supra note 8, at 862-863.
39 United States v. Miles, 360 F.3d 472, 480 (5th Cir. 2004)
any authority to act on behalf of a physician in selecting the particular home health provider…

The payments from APRO to Premier were not made to the relevant decision-maker as an inducement or kickback for sending patients to APRO.” In a footnote, the court acknowledged that the defendant’s contact may have violated the “arranging for or recommending” prong of the Anti-Kickback Statute. However, because the convictions were only for violations of the first prong, which prohibits patient referrals, the court overturned those convictions.40

B. The Stark Law

The Stark Law provides that if a physician (or a member of the physician’s immediate family) has a financial relationship with an entity, (1) the physician may not make a referral to the entity for the furnishing of designated health services for which payment may be made by Medicare and (2) the entity may not present, or cause to be presented, a claim for a designated health service rendered pursuant to a prohibited referral, unless a specific exception is met.41 Sanctions for violating the Stark Law include denial of payment, refunding amounts received for services provided pursuant to prohibited referrals, civil monetary penalties up to $15,000 per item or service improperly billed, and exclusion from federal healthcare programs. The Stark Law also provides for a penalty of up to $100,000 for a scheme intended to circumvent the Stark Law’s prohibitions.

Unlike the Anti-Kickback Statute, the Stark Law is a strict liability statute that does not take intent into account. Regardless of providers’ intentions, arrangements that trigger the Stark Law and fail to meet all of the elements of an applicable exception will violate the Stark Law. Further, an arrangement that satisfies a Stark Law exception or safe harbor may still violate the

40 Id. at 480-481; but see United States v. Polin, supra note 25 (affirming convictions of a nurse and physician who paid a pace-maker sales representative a per-patient fee for directing patients to their cardiac monitoring services where they had been charged with violating the paying kickbacks for “referring patients” portion of the statute rather than for “recommending or arranging” the purchase of services.)
Anti-Kickback Statute if it does not also meet an Anti-Kickback safe harbor. The Stark Law defines “designated health services” to include a range of items or services, including, among others, clinical laboratory services, physical therapy services, radiology services, inpatient and outpatient hospital services, and durable medical equipment and supplies.42

The Stark Law may be implicated by a marketing or consulting arrangement where a physician markets on behalf of an entity that furnishes designated health services or vice versa. For example, physicians may be paid to market on behalf of hospitals with which they are affiliated. Likewise, advertising campaigns by hospitals to market their physicians may constitute remuneration to the physicians.

To the extent a marketing arrangement implicates the Stark Law, healthcare providers should structure it to meet an exception to the Stark Law. One of the exceptions to the Stark Law that may be of use to physicians who may be marketing on behalf of an entity that provides designated health services is the *bona fide* employment relationship exception.43 The employment relationship exception protects any amount paid by an employer to a physician who has a *bona fide* employment relationship with the employer for the provision of services if certain conditions are met, including: (1) the employment is for identifiable services; (2) the remuneration is consistent with the fair market value of the services and not determined in a manner that takes in account, directly or indirectly, the volume or value of any referrals by the referring physician; and (3) the remuneration is provided under an agreement that would be commercially reasonable even if the physician made no referrals to the employer.44

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42 “Designated health services” is defined to include clinical laboratory services, physical therapy, occupational therapy, speech pathology, radiology (including MRI, CT, X-ray and ultrasound), radiation therapy services and supplies, durable medical equipment and supplies, parenteral and enteral nutrients, prosthetics, orthotics and prosthetic devices, home health services, outpatient prescription drugs (reimbursed under Medicare Part B or Part D), and inpatient and outpatient hospital services. See 42 U.S.C. § 1395nn(h)(6); 42 C.F.R. § 411.351.
43 42 U.S.C. § 1395nn(e)(2); 42 C.F.R. § 411.357(c).
44 *Id.*
employment relationship exception may prove useful in arrangements in which a hospital or other healthcare facility seeks to engage its physician employees to assist with marketing efforts.

Aside from the employment relationship exception, the personal service arrangements exception to the Stark Law may also provide protection to marketing arrangements between healthcare providers and entities that furnish designated health services. To satisfy the personal services arrangements exception, the following conditions must be met:

1. The arrangement is set forth in writing that specifies the services provided and is signed by both parties;
2. The arrangement includes all of the services the physician will provide to the entity;
3. The aggregate services under the arrangement do not exceed what would be reasonable and necessary for a legitimate business purpose;
4. The arrangement is for at least one year;
5. The compensation for the arrangement is set in advance, does not exceed fair market value, and is not determined in a manner that takes into account the volume or value of any referrals or other business generation between the physician and the entity; and
6. The arrangement does not provide for services in violation of any federal or state statute.

In addition to these exceptions, healthcare providers and facilities may also consider the potential application of the nonmonetary compensation exception to protect compensation in the form of items or services of relatively low value, although the exception is quite limited. The exception protects compensation from an entity to a physician in the form of items of services other than cash or cash equivalents that does not exceed an aggregate of $300 per calendar year (adjusted for inflation) provided that: (1) the compensation is not determined in a manner that takes into account the volume or value of referrals or other business generated by the referring physician; (2) the compensation is not solicited by the physician or the physician’s practice.

46 Id.
47 42 C.F.R. § 411.357(k).
48 For calendar year 2013, the compensation limit is $380. See CMS, CPI-U Updates, http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/CPI-U_Updates.html.
(including employees and staff members); and (3) the compensation arrangement does not violate the Anti-Kickback Statute (or any federal or state law or regulation governing billing or claims submission). 49

While in comparison to the Anti-Kickback Statute, the Stark Law may be less likely to be implicated by marketing activities, its potential application must be carefully considered by healthcare providers, as any arrangement that implicates the prohibition must find refuge in an exception in order to avoid a violation. Providers and the facilities with which they are affiliated should evaluate any proposed arrangement in which the provider may be construed as marketing on behalf of the facility or vice versa.

C. The Civil Money Penalty Law

Healthcare providers must also carefully consider whether a proposed marketing activity involves the offer of “remuneration” to Medicare or Medicaid beneficiaries in an effort to influence the beneficiaries’ choice in selecting healthcare providers. The CMP Law provides for, among other things, the imposition of civil monetary penalties against any person who offers to or transfers remuneration to any individual eligible for benefits under Medicare or Medicaid that the person knows or should know is likely to influence the individual’s selection of a particular provider, practitioner, or supplier of any item or service for which payment may be made by Medicare or Medicaid. 50 In addition to the imposition of civil monetary penalties, violations of the CMP Law may lead to exclusion from participation in federal healthcare programs.

49 42 C.F.R. § 411.357(k).
50 See 42 U.S.C. § 1320a-7a(a)(5).
The CMP Law defines “remuneration” to include “transfers of items or services for free or for other than fair market value.”\(^\text{51}\) Prior to the passage of the ACA, there were several limited exceptions to the “remuneration” ban, including free items or services of “nominal value” where each service or item was $10 or less and worth no more than $50 in the aggregate per year.\(^\text{52}\) In addition to the nominal value test, the ACA created four additional exceptions to the definition of remuneration, which allow providers more flexibility in providing certain gratuitous items or services to patients covered by Medicare or Medicaid.\(^\text{53}\) The ACA added the following new exceptions to the statutory definition of “remuneration”:

1. Remuneration which promotes access to care and poses a low risk of harm to patients and federal healthcare programs (as determined by the Secretary of HHS);

2. Items or services that (i) consist of coupons, rebates or other rewards\(^\text{54}\) from a retailer; (ii) are offered or transferred on equal terms available to the general public, regardless of health insurance status; and (iii) are not tied to the provision of items or services reimbursed in whole or in part by Medicare or Medicaid;

3. Items or services that (i) are not offered as part of any advertisement or solicitation; (ii) are not tied to the provision of services reimbursed in whole or in part by Medicare or Medicaid; (iii) are reasonably connected to the medical care of the individual; and (iv) are provided after determining in good faith that the individual is in financial need; and

4. Waiver by a PDP sponsor of a prescription drug plan under Medicare Part D, or a Medicare Advantage organization offering an MA-PD plan under Medicare Part C, of any copayment for the first fill of a covered part D drug, as long as it is a generic drug.\(^\text{55}\)

\(^{51}\) 42 U.S.C. § 1320a-7a(h)(i)(6).

\(^{52}\) Among the other exceptions is the provision of incentives to individuals to promote the delivery of preventive care. 42 U.S.C. § 1320a-7a(h)(i)(6)(d). The regulations implementing this provision define “preventive care” as any service that “(1) is a prenatal service or post-natal well-baby visit or is a specific clinical service described in the current U.S. Preventive Services Task Force’s Guide to Clinical Preventive Services, and (2) is reimbursable in whole or in part by Medicare or an applicable State health care program.” 42 C.F.R. § 1003.101.

\(^{53}\) ACA, Section 6402(d)(2)(B).


\(^{55}\) ACA, Section 6402(d)(2)(B).
While regulations have not yet been issued for the new exceptions, as of the date of this paper, these changes ostensibly grant providers more freedom to offer incentives for patients to adhere to their healthcare regimes. However, any incentive or marketing program that qualifies for an exception to the CMP Law must also not generate prohibited remuneration or referrals under the Anti-Kickback Statute and Stark Law.56

D. HIPAA and HITECH

All marketing arrangements must be structured to comply with the HIPAA privacy and security regulations, as amended by HITECH.57 The privacy and security regulations promulgated pursuant to HIPAA extensively regulate the use and disclosure of individually identifiable health information and require certain covered entities, including most healthcare providers, to implement administrative, physical, and technical safeguards to protect the security of such information. HITECH expands the scope of the HIPAA privacy and security regulations and extends the application of certain provisions of the regulations directly to certain entities that use individually identifiable health information on behalf of covered entities. HITECH also strengthens the enforcement provisions of HIPAA and significantly increases the amount of civil penalties that may be assessed for violations of HIPAA.

The HIPAA privacy regulations currently require that covered entities must obtain an authorization before sending marketing communications to individuals.58 Furthermore, if the covered entity receives remuneration, directly or indirectly, for its marketing activities, the

56 See OIG Adv. Op. No. 12-14 (Oct. 9, 2012) (proposed arrangement under which grocery store customers would earn rewards in the form of gasoline discounts based on the amount spent in the grocery store, including items purchased at in-store pharmacies, satisfied the CMP exception to “remuneration” while still potentially generating prohibited remuneration under the Anti-Kickback Statute).
57 See generally 45 C.F.R. pts. 160 to 164.
58 45 C.F.R. § 164.508(a)(3). Covered entities are not required to obtain an authorization for any use or disclosure of protected health information for marketing if the communication is in the form of: (1) a face-to-face communication made by a covered entity to an individual or (2) a promotional gift of nominal value provided by the covered entity. Id.
authorization must state as much.59 “Marketing” is defined under the privacy regulations as “a communication about a product or service that encourages recipients of the communication to purchase or use the product or service.”60 This definition specifically excludes certain communications related to a patient’s treatment, case management or care coordination, as well as recommendations of alternative treatments, therapies, or providers.61 Moreover, the provisions of the HIPAA privacy regulations that permit the use or disclosure of protected health information do not incorporate these exceptions to the definition of marketing. Thus, most healthcare providers’ marketing efforts, if they involve the use or disclosure of protected health information, must also meet an exception to the general prohibition against the use or disclosure of such information in the HIPAA privacy regulations (e.g., to carry out health care operations).

Historically, many have considered the vast majority of the communications that fit within the exceptions to the marketing definition (i.e., communications related to a patient’s treatment, case management, or care coordination, and recommendations of alternative treatments, therapies, or providers) to also fit within the definition of “health care operations.” However, HITECH clarifies when marketing communications may be considered health care operations and, in so doing, largely prohibits covered entities from obtaining financial remuneration for these types of communications without a valid authorization from the individual.62 HITECH does, however, include exceptions where: (1) the communication

60 45 C.F.R. § 164.501.
61 See id. It should be noted, however, that even though a particular communication does not constitute “marketing” under the HIPAA privacy regulations, it may implicate the Anti-Kickback Statute and/or other fraud and abuse laws. See HHS Office for Civil Rights Frequently Asked Questions at http://www.hhs.gov/ocr/privacy/hipaa/faq/marketing/291.html (“Although a particular communication under the Privacy Rule may not require patient authorization because it is not “marketing,” or may require patient authorization because it is “marketing” as the Rule defines it, the arrangement may nevertheless violate other statutes and regulations administered by the Department of Health and Human Services, Department of Justice, or other Federal or State agencies”).
describes only a drug or biologic that is currently being prescribed for the recipient of the communication and any payment received by the covered entity is reasonable in amount; (2) individual authorization is obtained; and (3) the communication is made by a business associate on behalf of the covered entity and the communication is consistent with the business associate agreement. The HHS Office for Civil Rights (“OCR”) has issued a proposed rule to implement these and other HITECH requirements. While the regulations have yet to be finalized, it is worth noting that, in the proposed rule, OCR has characterized its understanding of the legislative intent behind the HITECH changes as follows:

We believe Congress intended with these provisions to curtail a covered entity’s ability to use the exceptions to the definition of “marketing” in the [HIPAA privacy regulations] to send communications to the individual that were motivated more by commercial gain or other commercial purpose rather than for the purpose of the individual’s health care, despite the communication’s being about a health-related product or service.

The HIPAA privacy regulations also address the use of protected health information to perform fundraising activities. In general, a covered entity may use, or disclose to a business associate or to an institutionally related foundation, certain very limited protected health information (namely, demographic information and the dates on which healthcare services were provided to an individual) for fundraising purposes without an individual authorization. Covered entities that seek to use protected health information for fundraising activities must: (1) include a statement in their Notice of Privacy Practices; (2) include in any fundraising materials it sends to an individual a description of how the individual may opt out of receiving further fundraising communications; and (3) make reasonable efforts to ensure that individuals who

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63 Id.
65 Id. at 40884.
66 45 C.F.R. § 164.514(f)(1).
elect to opt out are not sent further communications. HITECH strengthens the individual’s right to opt out of fundraising communications and the OCR’s proposed rule to implement HITECH includes several provisions that would add further limits on covered entities’ fundraising communications.

III. Federal Telecommunications Laws and Regulations that Impact Providers’ Marketing Efforts

In addition to complying with those laws and regulations focused exclusively on the healthcare industry, healthcare providers must also consider the potential impact of telecommunications laws and regulations on their marketing activities, particularly when those activities involve telemarketing. Of particular relevance are the laws and regulations promulgated by the Federal Trade Commission ("FTC") and Federal Communications Commission ("FCC"). While following a recent update to the FCC’s rules, the agencies’ approaches to regulating telemarketing activity are substantially similar in certain key respects and include a significant exemption for certain healthcare-related telephone calls, healthcare providers and suppliers should have a clear understanding of how their marketing activities may implicate the agencies’ rules.

The FTC’s authority to regulate telemarketing practices derives in part from the Telemarketing Consumer Fraud and Abuse Prevention Act, which required the FTC to adopt rules to prohibit deceptive and abusive telemarketing acts or practices, including in particular “unsolicited telephone calls which the reasonable consumer would consider coercive or abusive of the consumer’s right to privacy.” The regulations promulgated by the FTC to implement

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67 45 C.F.R. § 164.514(f)(2).
this law are collectively referred to as the “Telemarketing Sales Rule.” In 2008, the FTC amended the Telemarketing Sales Rule to (1) prohibit sellers or telemarketers from making prerecorded telephone calls unless the seller or telemarketer had previously obtained the recipient’s signed, written consent to receive such calls; and (2) require that prerecorded telemarketing calls include an automated, interactive mechanism by which the recipient could opt out of receiving future prerecorded messages from the seller.

The FCC’s Telephone Consumer Protection Act of 1991 (the “TCPA”) also imposes restrictions on the use of the telephone network for unsolicited advertising by telephone and facsimile for the purpose of protecting consumers from unwanted calls. Among other things, the TCPA regulates the use of automated telephone equipment, including prohibiting non-emergency prerecorded calls to a residential line without the recipient’s “prior express consent.” However, the TCPA authorizes the FCC to enact exemptions to this prohibition in order to permit calls that are made for a noncommercial purpose and commercial calls that the FCC has determined neither adversely affect the recipient’s privacy rights nor transmit an unsolicited advertisement. The FCC has implemented the TCPA by also prohibiting other categories of non-emergency automated calls absent prior express consent, including the use of automatic telephone dialing systems or prerecorded messages when calling emergency telephone lines, healthcare facilities, wireless telephone numbers and services for which the recipient is charged for the call. While pursuant to the TCPA, the FCC has adopted company-specific “do not call” lists, as well as a national Do-Not-Call registry, calls to recipients with whom the caller

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70 16 C.F.R. § 310.1 et seq.
has an established business relationship are exempt from the prohibition against calls to residential lines.\(^76\)

On February 15, 2012, the FCC issued Report and Order 12-21 (the “2012 FCC Order”).\(^77\) The 2012 FCC Order was, in part, an effort to maximize consistency between the FCC’s rules and the FTC’s Telemarketing Sales Rule, while continuing to protect consumers from unwanted telemarketing calls pursuant to the TCPA. The 2012 FCC Order made three major changes to the FCC’s rules. First, it revised the rules to require prior express written consent for all autodialed or prerecorded telemarketing calls to wireless numbers and residential lines and, accordingly, eliminated the established business relationship exemption for such calls to residential lines while maintaining flexibility in the form of consent needed for purely informational calls. Second, it adopted rules applicable to all prerecorded telemarketing calls that allow consumers to opt out of future “robocalls\(^78\)” during such a call. Third, the 2012 FCC Order revised the rules to limit permissible abandoned calls on a per-calling campaign basis, in order to discourage intrusive calling campaigns. Of particular relevance for healthcare providers, the 2012 FCC Order also exempted from certain TCPA requirements prerecorded healthcare-related calls to residential lines that are subject to HIPAA.\(^79\) However, none of the FCC’s actions changed requirements for prerecorded messages that are non-telemarketing, informational calls, such as calls by or on behalf of tax-exempt non-profit organizations, calls for political purposes, and calls for charitable purposes.

\(^{76}\) See id.


\(^{78}\) The 2012 FCC Order refers to “telemarketing robocalls” generally as “unwanted autodialed or prerecorded telemarketing calls.” Id.

\(^{79}\) In the 2012 FCC Order, the FCC found that HIPAA’s existing protections “already safeguard consumer privacy, and we therefore do not need to subject these calls to our consent, identification, opt-out, and abandoned call rules.” The FCC went on to note as follows: “With respect to the privacy concerns that the TCPA was intended to protect, we believe that prerecorded health care-related calls to residential lines, when subject to HIPAA, do not tread heavily upon the consumer privacy interests because these calls are placed by the consumer’s health care provider to the consumer and concern the consumer’s health. Moreover, the exemption we adopt today does not leave the consumer without protection. The protections provided by HIPAA safeguard privacy concerns.” Id. (citations omitted). It should also be noted that in a 2008 amendment to the Telemarketing Sales Rule, the FTC also exempted prerecorded healthcare-related calls subject to HIPAA from its restrictions on such calls.
and calls for other noncommercial purposes, including those that deliver purely informational messages such as school closings.

Notwithstanding the seemingly broad exemption for healthcare-related calls “subject to HIPAA,” healthcare providers and suppliers should carefully consider the potential implications of the 2012 FCC Order on their marketing efforts. The FCC made clear in the 2012 FCC Order that “where the prerecorded health care-related call is not covered by HIPAA, as determined by HHS, restrictions imposed by the TCPA and our implementing rules will apply as the facts warrant.” Accordingly, we provide a brief review of the consent requirements and the required opt-out mechanism described in the 2012 FCC Order.

A. **Content and Form of Consent**

In finding that express written consent for all autodialed or prerecorded telemarketing calls to wireless numbers and residential lines is required, the FCC noted its previously asserted position that the term “signed” may include an electronic or digital form of signature, to the extent such form of signature is recognized as a valid signature under applicable federal or state contract law. Consistent with the FTC’s Telemarketing Sales Rule, the FCC noted that a consumer’s written consent to receive prerecorded telemarketing calls must be signed and sufficient to show that he or she: (1) received “clear and conspicuous disclosure” of the consequences of providing the requested consent, *i.e.*, that the consumer will receive future calls that deliver prerecorded messages by or on behalf of a specific seller; and (2) having received this information, agrees unambiguously to receive such calls at a telephone number the consumer designates. In addition, the written agreement must be obtained “without requiring, directly or

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80 Id.
81 See id. (citing 2003 TCPA Order, 18 FCC Rcd at 14043-44, para. 44 n.158).
82 Id.
indirectly, that the agreement be executed as a condition of purchasing any good or service.”\textsuperscript{83} Finally, in the 2012 FCC Order, the FCC concluded that written agreements obtained in compliance with the Electronic Signatures in Global and National Commerce Act (the “E-SIGN Act”)\textsuperscript{84} will satisfy the written consent requirement.

B. Opt-Out Mechanism for Prerecorded Calls

The FCC also adopted an automated, interactive opt-out requirement for autodialed or prerecorded telemarketing calls in the 2012 FCC Order, again aligning its approach with that taken by the FTC’s Telemarketing Sales Rule.\textsuperscript{85} Under the FCC’s prior rules, a consumer who did not wish to receive further prerecorded telemarketing calls could opt out of receiving such calls by dialing a telephone number (required to be provided in the prerecorded message) to register his or her do-not-call request. Specifically, the prior rules required that, at the beginning of all prerecorded message calls, the message identify the entity responsible for initiating the call (including the legal name under which the entity is registered to operate), and during or after the message, provide a telephone number that consumers can call during regular business hours to make a company-specific do-not-call request.\textsuperscript{86} In contrast, the FTC’s Telemarketing Sales Rule requires, with limited exception, that any prerecorded message call that could be answered by the consumer in person provide an interactive opt-out mechanism that is announced at the outset of

\textsuperscript{83} Id.

\textsuperscript{84} Congress enacted the Electronic Signatures in Global and National Commerce Act (E-SIGN Act) to “facilitate the use of electronic records and signatures in interstate or foreign commerce” by granting legal effect, validity, and enforceability to electronic signatures, contracts, or other records relating to transactions in or affecting interstate or foreign commerce. 15 U.S.C. § 7001 et seq. (preamble); see 15 U.S.C. § 7001(a). The E-SIGN Act defines an “electronic signature” as “an electronic sound, symbol, or process attached to or logically associated with a contract or other record and executed or adopted by a person with the intent to sign the record.” 15 U.S.C. § 7006(5). It further defines an “electronic record” as “a contract or other record created, generated, sent, communicated, received, or stored by electronic means.” 15 U.S.C. § 7006(4).

\textsuperscript{85} FCC Report and Order 12-21, 27 FCC Red 1830 (Feb. 15, 2012).

\textsuperscript{86} Id. (citing 47 C.F.R. § 64.1200(b)).
the message and is available throughout the duration of the call. The opt-out mechanism, when invoked, must automatically add the consumer’s number to the seller’s do-not-call list and immediately disconnect the call. Where a call could be answered by the consumer’s answering machine or voicemail service, the message must also include a toll-free number that enables the consumer to subsequently call back and connect directly to an autodialed opt-out mechanism.

With the 2012 FCC Order, the FCC adopted the same approach as that taken by the FTC with respect to an opt-out mechanism. The FCC now requires that any prerecorded call that could be answered by a person provide an interactive opt-out mechanism that is announced at the outset of the call and is available throughout the call. In addition, once the opt-out mechanism is invoked, the call must be disconnected immediately and the person’s number must automatically be added to the seller’s do-not-call list. Finally, where a call could be answered by the person’s answering machine or voicemail service, the message must also include a toll-free number that enables the person to subsequently call back and connect directly to an autodialed opt-out mechanism.

IV. Special Considerations for DMEPOS Suppliers Regarding Telemarketing

In addition to considering the risks and limitations imposed by all of the foregoing laws and regulations, suppliers of DMEPOS must structure their marketing practices to comply with a statutory restriction that applies specifically to DMEPOS suppliers. Section 1834(a)(17)(A) of the Social Security Act prohibits DMEPOS suppliers from making unsolicited telephone calls to Medicare beneficiaries regarding the furnishing of a covered item, except under three limited

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87 Id. (citing 73 Fed. Reg. at 51185).
88 Id.
89 Id.
90 Id.
91 Id.
circumstances: (1) the beneficiary has given written permission to the supplier to make contact by telephone; (2) the contact is regarding a covered item that the supplier has already furnished; or (3) the supplier has furnished at least one covered item to the beneficiary during the preceding 15 months. In addition, Section 1834(a)(17)(B) of the Social Security Act\(^93\) specifically prohibits payment to a supplier that knowingly submits a claim generated pursuant to a prohibited telephone solicitation. Furthermore, if a supplier knowingly makes prohibited telephone solicitations to such an extent that the supplier’s conduct establishes a “pattern of contacts in violation of [the prohibition],” then the Secretary of HHS shall exclude the supplier from participation in federal healthcare programs.\(^94\) In addition to this statutory restriction, DMEPOS suppliers must also comply with a substantially similar regulatory restriction on the direct solicitation of Medicare beneficiaries found in the Medicare DMEPOS supplier standards.\(^95\)

Both the OIG and CMS have issued interpretive guidance regarding the telemarketing prohibition. First, in its 1999 Compliance Program Guidance for the DMEPOS Industry, the OIG highlighted the telemarketing prohibition in its general discussion of marketing practices and suggested that DMEPOS suppliers’ policies and procedures reflect the prohibition.\(^96\) In March 2003, the OIG issued a Special Fraud Alert concerning telemarketing by DMEPOS suppliers (the “2003 Special Fraud Alert”).\(^97\) In the 2003 Special Fraud Alert, the OIG indicated that it had received information that some DMEPOS suppliers had continued to use independent marketing firms to make unsolicited telephone calls to Medicare beneficiaries to market DMEPOS. The OIG observed that the unsolicited telemarketing by a DMEPOS supplier to a

\(^{93}\) 42 U.S.C. § 1395m(a)(17)(B).
\(^{94}\) 42 U.S.C. § 1395m(a)(17)(C).
\(^{95}\) 42 C.F.R. § 424.57(c)(11).
\(^{96}\) 64 Fed. Reg. 36368, 36380 (July 6, 1999).
Medicare beneficiary is prohibited regardless of whether contact with the beneficiary is made by the supplier directly or by another party acting on the supplier’s behalf, and stated that “[s]uppliers cannot do indirectly that which they are prohibited from doing directly.”\textsuperscript{98} Furthermore, the OIG noted that DMEPOS suppliers are responsible for verifying that any marketing activities performed by third parties on the supplier’s behalf do not involve prohibited activity and that any information purchased from third parties was neither obtained, nor derived, from prohibited activity.\textsuperscript{99} Finally, in the 2003 Special Fraud Alert, the OIG also took the position that if a claim for payment is submitted for items or services generated by a prohibited solicitation, both the DMEPOS supplier and the third-party telemarketer are potentially liable for criminal, civil, and administrative penalties for causing the filing of a false claim.\textsuperscript{100}

In January 2010, the OIG revisited the issue of telemarketing by DMEPOS suppliers and issued an Updated Special Fraud Alert on the subject (the “2010 Updated Special Fraud Alert”).\textsuperscript{101} The 2010 Updated Special Fraud Alert largely reiterated the 2003 Special Fraud Alert; however, in the 2010 Updated Special Fraud Alert, the OIG also took the position that a physician’s preliminary written or verbal order prescribing DMEPOS for a Medicare beneficiary may not be used as a substitute for the written consent of the Medicare beneficiary, thereby implying that DMEPOS suppliers may not contact Medicare beneficiaries by telephone based solely on treating physicians’ preliminary written or verbal orders without violating the telemarketing prohibition. Because the practice by suppliers of contacting beneficiaries directly to arrange for the delivery of DMEPOS following the suppliers’ receipt of orders from

\textsuperscript{98} Id.
\textsuperscript{99} Id.
\textsuperscript{100} Id.
\textsuperscript{101} 75 Fed. Reg. 2105 (Jan. 14, 2010).
physicians was widespread and longstanding, the 2010 Updated Special Fraud Alert drew sharp criticism from industry representatives.\textsuperscript{102}

Shortly after the OIG’s publication of the 2010 Updated Special Fraud Alert, CMS issued guidance on the subject of telemarketing in the form of several Frequently Asked Questions posted on its website (the “2010 CMS FAQs”).\textsuperscript{103} The 2010 CMS FAQs addressed a number of issues concerning the telemarketing prohibition, including whether a DMEPOS supplier is considered to have made an “unsolicited” contact when it contacts a beneficiary on the basis of its receipt of a physician order. In the 2010 CMS FAQs, CMS took a more nuanced position than that taken by the OIG in its 2010 Special Fraud Alert, providing as follows:

> If a physician contacts a supplier on behalf of a beneficiary with the beneficiary’s knowledge, and then a supplier contacts the beneficiary to confirm or gather information needed to provide that particular covered item (including delivery and billing information), then that contact would not be considered “unsolicited”. Please note that the beneficiary need only be aware that a supplier will be contacting him/her regarding the prescribed covered item, recognizing that the appropriate supplier may not have been identified at the time of consultation.\textsuperscript{104}

CMS made clear, however, that if a DMEPOS supplier contacts a beneficiary solely on the basis of a physician order, but the beneficiary did not know that the physician would contact the supplier on the beneficiary’s behalf, the contact would be “unsolicited.”\textsuperscript{105} Thus, provided that the beneficiary knew that the physician would be contacting a supplier (and not necessarily the particular supplier who would provide the covered item), the supplier (or physician) would not be required to obtain the beneficiary’s prior written consent.


\textsuperscript{103} The OIG has made a copy of the 2010 CMS FAQs available at https://oig.hhs.gov/fraud/docs/alertsandbulletins/fraudalert_telemarketing_DME.pdf.

\textsuperscript{104} Id. (emphasis original).

\textsuperscript{105} Id.
In the 2010 CMS FAQs, CMS also provided guidance on several other issues concerning
telemarketing practices by DMEPOS suppliers. For one, CMS clarified that the supplier is not
required to collect and maintain documentation from the physician reflecting that the physician
contacted the supplier with the beneficiary’s knowledge, noting that whether such documentation
should be obtained would be a business decision for the supplier. CMS also noted that if a
supplier makes solicited contact with a beneficiary for a particular covered item, the supplier is
prohibited from attempting to solicit the purchase of additional covered items during the same
contact. However, once the supplier has provided the covered item to the beneficiary, it may
then subsequently contact the beneficiary to offer other covered items in accordance with the
exceptions set forth in the statute. Finally, CMS indicated that a supplier does not make an
“unsolicited” contact when it returns a beneficiary’s phone call.

In August 2010, CMS published a final rule to clarify, expand, and add to certain of the
regulatory requirements DMEPOS suppliers must meet to establish and maintain Medicare
billing privileges (the “2010 Final Rule”). In the preamble to the 2010 Final Rule, CMS
provided commentary consistent with the 2010 CMS FAQs released earlier that year. More
specifically, CMS offered the following guidance with respect to situations in which a DMEPOS
supplier contacts a beneficiary on the basis of a physician order:

[A] DMEPOS supplier may not contact a beneficiary based solely on a physician
order. However, a supplier may contact a beneficiary if a physician contacts a
DMEPOS supplier on behalf of a beneficiary with the beneficiary’s knowledge,
and then a supplier contacts the beneficiary to confirm or gather information
needed to provide that particular covered item (including delivery and billing
information). In that instance, the contact would not be considered a direct
solicitation and therefore, would not implicate the standard set forth at [42 C.F.R.
§ 424.57(c)(11)].

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107 Id. at 52639.
However, CMS also expanded the definition of “direct solicitation” within the telemarketing prohibition to not only include solicitation by telephone, but also solicitation by “computer, e-mail, instant messaging or in-person contact.”\textsuperscript{108} As a result, DMEPOS suppliers were required to meet one of the three exceptions described above in order to solicit Medicare beneficiaries regarding the furnishing of a covered item by phone, computer, or in-person contact.

In apparent response to negative industry feedback, in April 2011, CMS proposed a revision to its expanded definition of “direct solicitation,” noting that it had “discovered that implementation of the expanded portions of this provision as written is unfeasible.”\textsuperscript{109} The proposed rule removed the definition of “direct solicitation” from the regulations and clarified that the prohibition was limited to telephonic contact. However, CMS noted that it would continue to watch the issue closely:

\begin{quote}
Although we are proposing to modify the supplier standard on direct solicitation at \textsuperscript{[42 C.F.R.] § 424.57(c)(11)}, we will continue to actively monitor the issue of potentially unwanted and unsolicited communications between DMEPOS suppliers and beneficiaries. In the event we believe that we need to take action to limit these types of communications, we will engage in further rulemaking to address this concern.\textsuperscript{110}
\end{quote}

In March 2012, CMS issued a final rule that finalized the removal of the definition of “direct solicitation” from the regulatory restriction found in the Medicare DMEPOS supplier standards (the “2012 Final Rule”).\textsuperscript{111} In the 2012 Final Rule, CMS also revisited the issue of whether DMEPOS suppliers may contact beneficiaries upon receipt of a physician order as long as the beneficiary has been made aware that he or she will be contacted by a DMEPOS supplier. However, CMS’s comments in the 2012 Final Rule raise new questions about an issue that appeared to have been resolved in the 2010 Final Rule. More specifically, CMS recounted a

\textsuperscript{108} \textit{id.} at 52648 (modifying 42 C.F.R. § 424.57(a)).
\textsuperscript{110} \textit{id.}
commenter’s request that the Medicare DMEPOS supplier standards be revised to allow suppliers to contact beneficiaries upon receipt of a physician order (provided, again, that the beneficiary has been made aware of the supplier’s pending contact). The commenter also cited the statement in the 2010 CMS FAQs supporting such a standard. CMS, however, declined to opine on the issue, noting that it had not specifically solicited comments on the issue. While CMS declined to revise the supplier standards to directly address the issue of contacting beneficiaries on the basis of a physician order, it did refer to the frequently asked questions portion of its website, which contains the statement quoted above the 2010 CMS FAQs. In addition, in responding to another commenter, CMS indicated that certain of its commentary in the 2010 Final Rule on the issue “still reflects our policy with regard to this provision.”

Aside from the issue of whether a contact is unsolicited for purposes of the telemarketing prohibition described above, DMEPOS suppliers also need to consider the issue of recording calls when contacting Medicare beneficiaries by telephone. Where a supplier elects to record its calls to Medicare beneficiaries, the supplier must comply with the applicable state and federal law requirements concerning consent to record. While this paper will not review particular state law requirements, a general consideration that DMEPOS suppliers should account for is whether their telemarketing activities are directed to beneficiaries in a “two party” or “one party” consent state.

In general, when all parties are in the same state, that state’s law regarding recording telephone calls applies. When the parties are in two or more different states at the time of the call, three bodies of law are potentially implicated: the law of the caller’s state, the law of the recipient’s state, and federal law. Federal law generally requires the prior consent of only one

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112 Id. at 14990.
114 77 Fed. Reg. at 14991.
participating party for recording a telephone conversation (unless the recording is done for a criminal or tortious purpose). While the majority of states subscribe to the “one party” rule, the remaining states require the consent of all parties before a telephone conversation can be recorded. Depending on the state, the individual or entity who records a telephone call without the consent of all parties may be subject to criminal and/or civil penalties.

DMEPOS suppliers must also consider the timing of the telemarketing calls, as the laws of some states restrict the types of calls that may occur on Sundays. In general, and with one exception (the State of Utah), state laws do not prohibit telephone solicitations on Sundays when the call is placed by a live operator and either (1) there is a preexisting business relationship between the caller and the call recipient, or (2) the call recipient has given consent to receive the telephone call from the caller prior to the initiation of the call. However, some states prohibit the use of an auto-dialer on Sundays when the auto-dialer leaves a recording.

While telemarketing can be an efficient tool for DMEPOS suppliers to reach Medicare beneficiaries, suppliers must be attentive to the unique constraints placed on such practices and design their telemarketing activities accordingly. As noted in the OIG’s 2003 Special Fraud Alert, if a claim for payment is submitted for items or services generated by a prohibited solicitation, the DMEPOS supplier and any third-party telemarketer used by the supplier are potentially liable for criminal, civil, and administrative penalties for causing the filing of a false claim. In addition, because the statutory prohibition expressly provides that a pattern of inappropriate solicitations may lead to exclusion from federal healthcare programs, DMEPOS suppliers should ensure that their policies do not invite practices that may result in systematic violations of the law.

V. Practical Guidance for Ensuring Compliance

Before entering into any arrangement for marketing, advertising, or similar communications services, healthcare providers should carefully consider how the arrangement must be structured in order to avoid running afoul of the applicable laws. While the facts and circumstances of each particular marketing arrangement require thoughtful review, the following general guidance may assist healthcare providers in structuring marketing arrangements in a manner that complies with the legal framework described above:

- Providers should structure marketing arrangements to meet safe harbors under the Anti-Kickback Statute, such as the employment or personal services and management contracts safe harbors.

- Providers and the facilities with which they are affiliated should evaluate any proposed arrangement in which the provider may be construed as marketing on behalf of the facility or vice versa, and if so, whether the arrangement implicates the Stark Law. If a marketing arrangement appears to implicate the Stark Law, providers (and entities furnishing designated health services) should structure the arrangement to meet an exception under the Stark Law, such as the employment relationship exception, personal services arrangements exception, or nonmonetary compensation exception.

- Providers should not appear to endorse certain healthcare products or services in order to avoid “white coat” marketing.

- Any payments under a marketing arrangement should be for fair market value for the services rendered. Providers should ensure appropriate documentation of the fair market value determination, as well as the performance of the services.

- Payments under a marketing arrangement should not include success fees or compensation that otherwise reflects the generation of business by the healthcare provider.

- Providers should ensure that their business rationale is thoughtful, thorough and does not include any intent to inappropriately induce the purchase of items or services reimbursable by federal or state healthcare programs.

- Providers should not provide gifts to potential referral sources.
• Providers should ensure that suppliers and their sales agents compensate them only for providing actual, reasonable, and necessary services. Arrangements should not be merely token programs created to disguise otherwise improper payments.

• Providers should consider whether a proposed marketing activity may be viewed as offering or paying “remuneration” (as defined with reference to the CMP Law) to Medicare or Medicaid beneficiaries in an effort to influence the beneficiaries’ choice in selecting healthcare providers.

• Providers should tailor their consulting or marketing services to conform to the requirements of the HIPAA privacy regulations. In particular, where protected health information is to be used as part of a marketing activity, healthcare providers should ensure that adequate individual authorization has been obtained or, if not, that the activity is exempt from the provisions concerning marketing. Healthcare providers should also be mindful of the potential for change in the marketing standards with the release by OCR of final rules implementing HITECH.

• Providers and suppliers should carefully consider the potential application of the FCC’s and FTC’s rules concerning telemarketing activities and, in particular, whether the exemptions for healthcare-related calls subject to HIPAA apply to any proposed telemarketing practice.

• DMEPOS suppliers should ensure that their policies and procedures specifically restrict telemarketing activities to comply with the federal restriction on telephonic solicitation of Medicare beneficiaries regarding the furnishing of a covered item. In particular, if the supplier has not previously furnished a covered item to the beneficiary within the preceding 15 months, the supplier should first ensure that the beneficiary has given written permission to the supplier to make contact by telephone.

• If a DMEPOS supplier seeks to contact a Medicare beneficiary on the basis of contact it receives from a physician, it should consider either requesting documentation confirming that the physician contacted the supplier with the knowledge of the beneficiary or requesting that the physician confirm that he or she has apprised the beneficiary of the pending contact by the DMEPOS supplier.

• If DMEPOS suppliers contract with third-party firms to conduct telemarketing activities, the suppliers should ensure that the contracts with the firms clearly obligate the firms to perform in compliance with the federal restriction on telephonic solicitation of Medicare beneficiaries regarding the furnishing of a covered item. In addition, suppliers should reserve (and use, as necessary) the right to audit the practice of third-party telemarketing firms to ensure compliance.

• Healthcare providers and DMEPOS suppliers should carefully consider the potential application of state consumer protection and telecommunications laws in the evaluation of any proposed telemarketing program.