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THAT OTHER PROVISION OF THE ANTI-KICKBACK STATUTE:

Should Plaintiffs and the Government Reconsider its Potential Application and Benefits?

Andrew S. Feldman, Esq.
Feldman Firm PLLC
Miami, FL

Introduction

The federal Anti-Kickback Statute ("AKS") is a criminal statute containing *two* provisions. The first criminalizes the offering and paying of "remuneration" – cash and other accoutrements – to anyone in exchange for *referrals of* Medicare or Medicaid business and states in pertinent part:

- Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—
- in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
- in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program....[1]

The second provision of the AKS criminalizes conduct which is separate and apart from referrals and prohibits paying or receiving any remuneration in return for recommending purchasing, recommending ordering, or arranging for ordering or purchasing any items or services which are reimbursable by Medicare or Medicaid, and states in pertinent part:

- Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—
- to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
- to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program....[2]

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William W. Horton

Pay No Attention to the Lawyer(s) Behind the Curtain

As I write this column, it's less than a month after what may have been the most successful Washington Health Law Summit ever. By the time you read it (or at least have the opportunity to read it; I have no illusions about the size of my fan base), it will be nearly time for the 17th Annual Conference on Emerging Issues in Healthcare Law, known to the cognoscenti as "EMI", in sunny San Diego. Even now the finishing touches are being put on the 2016 Antitrust in Healthcare Conference, slated for May, and the Physicians Legal Issues Conference in June. All of these meetings offer cutting-edge educational programs, tremendous networking opportunities, and some great chances to have fun with friends new and old from around the country.

You come to one or more – or all – of these programs, and, if all goes well, things go smoothly and the sessions, receptions and networking breaks transition seamlessly from one to the next. You hear some great speakers, perhaps get exposed to some perspectives you don't regularly hear, and get insights that you can put to work for your clients or employers as soon as you get home. It's like – dare I say it? – magic.

That magic, the meetings that we hope appear to you to be running as effortlessly as a well-oiled machine, is in fact the work of our fantastic Section staff and – the focus of this column – volunteer leaders just like you who serve as the planning committees for our CLE programs. In order to bring you two or three days of education, fellowship and fun, our program planning committees work almost year-round, with each committee member putting in what can often be dozens of hours of volunteer time aimed at giving you the best programs your CLE dollar can buy.

Let's look at the EMI planning committee as an example. The work of the 2017 EMI planning committee will begin almost as soon as the 2016 program is done, with this year's planning committee co-chairs and other committee members reviewing your evaluations of EMI 2016 and discussing with the staff and Section leadership what worked, what didn't work, what can be improved upon and what we've learned this year that will help us make the program better next year. Meanwhile, Joyce Hall and Hilary Young, your 2015-2016 Chair-Elect and

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This second provision of the AKS potentially criminalizes a wide array of marketing arrangements since "recommending purchasing, leasing, or ordering" is the very essence of marketing. Yet, in practice, prosecutors seldom, if ever, allege a violation of the "recommending purchasing, leasing, or ordering" provision of the statute as the basis for a criminal count in an indictment. Similarly, while a claim that includes items or services resulting from a violation of the AKS is a *per se* violation of the False Claim Act ("FCA"), relators' counsel rarely, if ever, use the "recommending purchasing, leasing, or ordering" provision of the statute as a basis for alleging a violation of the FCA. As such, the federal jurisprudence interpreting this provision of the AKS is virtually non-existent.

This article will first discuss the "recommending purchasing, leasing, or ordering" provision of the AKS and the existing case law interpreting that provision of the AKS. Next, the article will argue that, in practice, plaintiffs and prosecutors have consistently ignored and substantially under-utilized the "recommending purchasing, leasing, or ordering" provision in criminal prosecutions and *qui tam* actions in comparison to its companion provision prohibiting *referrals*. Lastly, the article will analyze some of the underlying policy concerns that may have contributed to the lackluster enforcement of this apparently forgotten provision of the statute and the dearth of federal criminal and FCA cases addressing its application.

Recommending Purchasing, Leasing, or Ordering Provision of the AKS

More than twenty years ago, the Office of the Inspector General ("OIG") for the Department of Health and Human Services ("HHS") declared, unequivocally, that "on its face" the "recommending purchasing, leasing, ordering" provision of the AKS "prohibits the 'offering or acceptance of remuneration,' *inter alia*, for the purposes of 'arranging for or recommending purchasing, leasing, or ordering any… service or item' payable by Medicare or Medicaid."[3] Because "recommending purchasing" is a core element of any marketing arrangement, and because the OIG was concerned with "many instances where promoters or consultants have become involved in marketing activities that encourage health care providers and others to violate the statute,"[4] "remuneration" included compensation that was received in return for the performance of sales and marketing activities.

Recognizing that many, seemingly innocuous sales and marketing arrangements might violate this second provision of the AKS, and therefore expose individuals and organizations to potential *qui tam* lawsuits, or worse, criminal prosecution, Congress established certain statutory exceptions to the AKS and HHS promulgated several regulatory safe harbors to the AKS.[5]

For instance, Congress fashioned a statutory exception which exempts "remuneration" received by bona fide employees[6] pursuant to a written employment agreement from liability under the AKS. In addition, a regulatory safe harbor, known as the personal services and management safe harbor, was promulgated to immunize "remuneration" paid to an independent contractor or separate organization as long as *seven* rigorous requirements are met.[7] One crucial requirement of the personal services and management safe harbor to the AKS, which is often overlooked, is that the *aggregate* compensation must be set in advance.[8]

Nonetheless, even if a particular sales and marketing arrangement does not satisfy either a particular safe harbor or an exception, the arrangement should not technically violate the AKS unless a single purpose of the remuneration is to induce or reward future referrals of items or services payable by Medicare or Medicaid.[9] Furthermore, the government must still prove beyond a reasonable doubt that the person acted "willfully." "Willfully" means that the act was committed voluntarily and purposely, with the intent to do something the law forbids; that is to say, with bad purpose either to disobey or disregard the law.[10] While a person must have acted with the intent to do something the law forbids in order to act "willfully," the person need not know what specific law or rule his or her conduct violates."[11]

Applicable Law Addressing the Second Provision of the AKS

However, there has been limited jurisprudence interpreting the "recommending purchasing, leasing, or ordering" provision of the AKS.

United States v. Miles and Federal Criminal Prosecutions Under 42 U.S.C. Sections 1320a-7b(b)(1)(B), (b)(2)(B)

United States v. Miles[12] is one of the only federal criminal cases to address the application of the "recommending purchasing, leasing, or ordering" provision of the AKS, but it did so, fleetingly, in a footnote. Further, in *Miles*, the government did not file any criminal charges against members of the marketing entity at issue; therefore, the court's abbreviated discussion of the application of the second provision of the statute was limited to the billing entity, a home healthcare company.

In *Miles*, several owners of a home healthcare company, Affiliated Professional Home Health ("APRO") were convicted of the *first provision* of the AKS and mail fraud at trial. The owners were convicted of violating the AKS based on a marketing

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arrangement between APRO and a public relations company, Premier, performing sales and marketing services on APRO's behalf. The defendants had hired Premier to provide literature and advertising materials to physicians about their services. Premier was paid $300 for each client that physicians referred to APRO. APRO then billed Medicare. According to the government (and the jurors), this arrangement violated the AKS.

On appeal, the defendants argued convincingly that the per-patient payments made to Premier were not kickbacks since Premier was simply engaged in supplying promotional materials to physicians on defendants' behalf, and therefore, was incapable of making "referrals" to defendants in violation of the AKS.[13] The court agreed, reasoning that Premier "had no role in selecting the particular home health care provider" and the payments were "not made to the relevant decision-maker as an inducement or kickback for sending patients" to defendants.[14] Nonetheless, the court also noted that there are "certain situations where payments made to non-doctors would fall within the scope of the statute."[15]

Realizing, perhaps, that the AKS conviction rested on shaky grounds and that the use of the first provision ("referrals") of the AKS was not the proper prosecutorial vehicle for criminalizing this marketing arrangement, the government argued for the first time on appeal that the defendants' payments to Premier violated the AKS under a "companion provision."[16] Unfortunately, the Fifth Circuit's substantive analysis of this alternative theory of prosecution was hidden in a footnote where the court in *Miles* opined that "[u]nder this line of reasoning, APRO's payments to Premier might have been "recommendations" to doctors who then "referred" patients to APRO. Thus, their payments to third parties such as Premier may only be prosecuted under subsection (B), while payments directly to primary care providers must be prosecuted under subsection (A.)."[17] The court also insisted that "we need not speculate on its extent in this opinion because APRO's activities did not run afoul of the Subsection A crime with which they were charged."[18]

The takeaway from *Miles* is that sales and marketing arrangements are susceptible to criminal prosecution. At trial, the *Miles* prosecutors also had the opportunity to persuade jurors to convict members of APRO of violating the "recommending purchasing, leasing, or ordering" provision of the AKS, but that theory of prosecution was never before the jurors or the court until the appeal to the Fifth Circuit. As such, an important lesson gleaned from *Miles* is that this second provision of the AKS was disregarded.

In addition to *Miles*, at least three other federal criminal prosecutions have involved a violation of the AKS "recommending purchasing, leasing, or ordering" provision, but not one of those cases specifically involved the type of promoting or marketing that was at issue in *Miles*.

In *United States v. Carroll*,[19] the U.S. Attorney's Office for the Southern District of Illinois filed a multi-count indictment against defendants Jo Ann Carroll and Brian Denny which included one count of violating the "recommending purchasing, leasing, or ordering" provision of the AKS[20] based on the defendants' offering of free medical supplies to a distributor of durable medical equipment to induce the distributor to purchase, lease, or order additional medical supplies. After filing an unsuccessful motion to dismiss the indictment,[21] the defendants each agreed to a factual basis for pleading guilty to one count of violating the "recommending purchasing, leasing, or ordering" provision of the AKS as follows:

> As a factual basis for the plea, the defendant admits that he knowingly and willfully offered and caused to be offered, covertly and overtly, remuneration to business called Southern Medical Distributors ("SMD"). The remuneration was ninety five enteral pumps. These ninety five pumps were valuable, and were offered and marketed to SMD at no charge, for free. One purpose of the remuneration offered and caused to be offered by the Defendant was to induce the purchase and order of related goods and items by SMD for which payment was to be made in whole and in part by the Medicare program….[22]

The above language in the plea agreement is significant because it highlights that the government established the factual basis for a conviction for a violation of the AKS without the necessity of showing that one purpose of the remuneration was to induce *referrals* where, as here, the purpose of the remuneration was to induce the purchase and order of medical supplies covered in whole or in part by Medicare.[23]

In *United States v. Yielding*,[24] the U.S. Attorney's Office for the Eastern District of Arkansas convicted Geoffrey Yielding at trial for violating the "purchasing and ordering" provision of the AKS. The evidence at trial amply demonstrated that Mr. Yielding, as a registered nurse employed by a physician at Baptist Medical Health Center, encouraged members at Baptist to order medical supplies (bone growth stimulators) from his wife's medical supply distributorship since each order entitled Mr. Yielding's wife to receive a commission. Therefore, in contrast to the marketing or promoting at issue in *Miles*, here Mr. Yielding's continuous efforts to induce

physicians to purchase supplies from his wife's company were the basis for the criminal prosecution.

And in *United States v. Terrero*,[25] the U.S. Attorney's Office for the Southern District of Florida persuaded jurors to convict defendant Marianela Terrero of two separate counts of violating the second provision of the AKS when Ms. Terrero made cash payments to Medicare beneficiaries to induce them to order skilled nursing, speech and occupational therapy services. At trial, the district court also specifically approved the following jury instructions with respect to the second provision of the AKS:

1. That the Defendant knowingly and willfully solicited or received remuneration – including a kickback, bribe, or rebate – directly or indirectly, overtly or covertly, in cash or in kind, as charged in the Indictment; and
2. That the Defendant solicited or received remuneration or a kickback in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or part under a Federal health care program.[26]

Thus, while *Carroll*, *Yielding*, and *Terrero* may represent outlier cases and, unlike *Miles*, did not involve the provision of sales or marketing services, the guilty verdicts in *Yielding* and *Terrero* and the unambiguous language in the plea agreement in *Carroll* show that future prosecutions (and convictions) premised on the "recommending purchasing, leasing, or ordering" provision of the AKS would not be unprecedented. Further, the jury instructions accepted in *Terrero* may broadly apply to a wide range of marketing or sales activities, including commissions-based sales arrangements, which are discussed in more detail below.

OIG Advisory Opinions

Advisory opinions issued by the OIG's Office of Chief Counsel are widely viewed as some of the leading authorities concerning the application of the safe harbors or statutory exceptions to the AKS. But, unlike federal district courts that view an AKS safe harbor defense as an affirmative defense to be raised at trial[27] and further limit their analyses of the AKS to whether or not a single purpose of the arrangement is to induce or reward referrals,[28] in deciding whether a proposed arrangement violates the second provision of the AKS, the Office of Chief Counsel is willing to engage in a three-part analysis.[29]

OIG Advisory Opinion 98-10 sharply illustrates this point.[30] In that opinion, the Office of Chief Counsel analyzed whether a sales contract between a sales agency and a manufacturer to submit bids and negotiate contracts on behalf of the manufacturer for the sale and distribution of disposable medical supplies to potential purchasers violated the AKS.

Under the arrangement, all purchasers were either a multi-hospital healthcare system or a group purchasing organization representing primarily hospitals and hospital systems. As compensation, each sales agent was paid a monthly commission of between 1 percent and 1.25 percent of invoiced amounts by the manufacturer, but the specific percentage for each purchaser was set in advance and the sales agency certified that the percentage represented fair market value. The contract was also the only financial arrangement between the sales agent and the manufacturer and neither the sales agency nor the manufacturer had any known financial arrangements with purchasers.

Significantly, the sales agency and the manufacturer also did not bill for or receive any payments from Medicare for the goods sold by the sales agency to the purchasers and the sales agents, on balance, had limited to no interaction with the ultimate decision makers. Instead, specific orders for goods under the purchasers' contracts were placed by the purchasers' purchasing agents directly with the manufacturer, and agents interacted exclusively with centralized purchasing departments of multi-hospital systems and group purchasing organizations. Agents had no contact with individual hospitals, physicians, or beneficiaries and did not contact or market to anyone in a professional position to make referrals or order goods or services on behalf of individual patients.

In evaluating the above financial arrangement, the Office of Chief Counsel first emphasized that:

> Sales agents are in the business of recommending or arranging for the purchase of the items or services they offer for sale on behalf of their principals, typically manufacturers, or other sellers. Accordingly, any compensation arrangement between a Seller and an independent sales agent for the purpose of selling health care items or services that are directly or indirectly reimbursable by a Federal health care program potentially implicates the anti-kickback statute, irrespective of the methodology used to compensate the agent. Moreover, because such agents are independent contractors, they are less accountable to the Seller than an employee. (other citations omitted). For these reasons, this Office has a longstanding concern with independent sales agency arrangements.[31]

Next, the Office of Chief Counsel concluded that the arrangement could not satisfy the personal services and management safe harbor under the AKS,[32] but was willing to conduct an additional review to determine whether there were certain characteristics that "appear to be associated

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with an increased potential for program abuse, particularly overutilization and excessive program costs" including the following:

1. Compensation based on percentage of sales;
2. Direct billing of a federal healthcare program by the seller for the item or service sold by the sales agent;
3. Direct contact between the sales agent and physicians in a position to order items or services that are then paid for by a federal healthcare program;
4. Direct contact between the sales agent and federal healthcare program beneficiaries;
5. Use of sales agents who are healthcare professionals or persons in a similar position to exert undue influence on purchasers or patients; or
6. Marketing of items or services that are separately reimbursable by a federal healthcare program (*e.g.*, items or services not bundled with other items or services covered by a DRG payment), whether on the basis of charges or costs.[33]

Based on an analysis of the above factors, the Office of Chief Counsel concluded that the sales arrangement did *not* pose a high risk of fraud and abuse.[34] Of critical importance, the OIG noted that while the sales agents' compensation was established by a percentage of the sales, none of the other factors triggering increased scrutiny was present.[35] Moreover, neither the sales agency nor the manufacturer billed a federal healthcare program for the goods being sold.[36] Finally, because the particular products being sold to hospitals were not separately reimbursable by a federal healthcare program, the costs of the items furnished to inpatients represented an expense to hospitals that must be covered by a fixed payment, and therefore, the risk of excessive costs to a federal healthcare program was offset by the inability of the purchaser to pass on the costs of the items purchased to a federal healthcare program.[37]

Notwithstanding the fact that the Office of Chief Counsel found that the sales arrangement in advisory opinion 98-10 did not pose a significant risk of fraud and abuse, the Office of Chief Counsel has continued to apply this multi-part approach in numerous advisory opinions and, in so doing, has consistently concluded that per-test payments and commissions received by sales and marketing professionals pose serious risks of fraud and abuse under the AKS.[38]

Therefore, the OIG's multi-factor test serves as a useful guidepost for evaluating arrangements which potentially violate the "recommending purchasing, leasing, or ordering" provision of the AKS, but the reality is that courts only accord deference to OIG advisory opinions.[39] They are not binding on federal or state courts, the Department of Justice, or the potential universe of aggrieved plaintiffs seeking relief in various judicial fora. Instead, they are only binding on the person or organization requesting the opinion from the OIG ("the requestor"), but may be viewed as informal guidance when the arrangement is found to be violative of the AKS.

Breach of Contract Cases

Given the paucity of federal criminal jurisprudence addressing the "recommending purchasing, leasing, or ordering" provision of the AKS, it should come as no surprise that some of the dispositive discussions with respect to its application lay hidden in decisions involving contractual disputes.[40]

In *Modern Medical Laboratory v. Smith-Kline Beecham, Inc.*,[41] Modern Medical Laboratory and International Clinical Labs, which was later acquired by SmithKline Beecham, entered into a Cooperative Management Agreement which provided that a division of International Clinical Labs would market, manage, and operate Modern Medical Laboratory's laboratory business and facilities in exchange for 90 percent of the revenue generated from Modern Medical Laboratory's customers and territory. Modern Medical Laboratory was to receive 10 percent of the revenue.

Modern Medical Laboratory filed a breach of contract lawsuit after SmithKline, upon acquiring International Clinical Labs, advised Modern Medical Laboratory that it would not make further payments pursuant to the Agreement because, in its view, the Agreement violated the AKS. Modern Medical Laboratory urged the court to find that the contract was legal because "only physicians (and in some instances, law enforcement personnel) can lawfully order medical testing and thus, that Modern Medical Laboratory is without power to refer individuals to the other laboratory for testing."[42] The court rejected this argument and granted summary judgment in favor of International Clinical Labs (SmithKline), reasoning that the contract violated the "recommending purchasing, leasing, or ordering" provision of the AKS because:

> [S]ubsection (B) prohibits receiving remuneration in return for arranging for the purchasing of any Medicaid-reimbursable service. As we read this subsection, it criminalizes broker-style arrangements whereby one entity receives remuneration for placing business with another entity. Under this subsection, it is irrelevant that a physician made the initial decision to purchase certain testing services.[43]

Likewise, *Med. Dev. Network Inc. v. Prof'l Respiratory Care/Home Equip. Servs.*[44] also invalidated a percentage-based commission arrangement that violated the AKS. In *Med. Dev. Network Inc.*, a durable medical equipment ("DME") distributor entered into a contract with a marketing firm which received commissions based on the volume of DME sold to medical providers and health clinics. Sometime thereafter, the marketing firm refused to continue performance pursuant to the contract and, consequently, became a defendant in a breach of contract action. Much like the court in *Modern Medical*, the court sided with the party that initially abandoned the allegedly violative arrangement.[45] The court further cautioned 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."[46]

More recently, in *Woundkair Concepts Inc. v. Medica-Rents*,[47] the court decided whether a marketing agreement violated the "recommending purchasing, leasing, ordering" provision of the AKS when Woundkair, the plaintiff, claimed that defendant Medica-Rents breached the marketing agreement requiring Woundkair to serve as the exclusive agent of Medica-Rents' medical equipment in order to avoid paying Woundkair commissions it earned for providing those marketing services. Medica-Rents eventually filed a motion for summary judgment urging the court to invalidate the marketing arrangement because it violated the AKS.

The court analyzed Medica-Rents' motion, finding that the marketing arrangement would "fall within the provision's [42 U.S.C. § 1320a-7b(b)(1)(B)] application if its performance required Woundkair to recommend Medica-Rents products to potential customers or to third parties who would in turn recommend Medica-Rents products to potential customers, if the payment for the products may come from Medicare."[48] However, the court denied Medica-Rents' motion for summary judgment, reasoning that there was not a "scintilla of evidence" to establish, as a matter of law, that Woundkair's contract required it to perform direct marketing on behalf of Medica-Rents.[49] To the contrary, in the court's view, the evidence adduced demonstrated that Woundkair's principals did not deal with potential purchasers or recommend purchasing Medica-Rents products and instead "merely educated" Medica-Rents' existing sales force to assist them in locating and identifying sales opportunities, notwithstanding the fact that Woundkair was paid a percentage of the revenues from the business generated by Medica-Rents' sales people.[50] Under this arrangement, the court added that Medica-Rents employees, not Woundkair, appear to be the "people doing the 'arranging' that is governed by the AKS."[51]

Woundkair therefore confirmed that certain sales and marketing activities that require recommending the purchase of Medicare products fall within the ambit of the AKS even though the court held as it did.[52] Indeed, the opinion strongly suggests that, if the principals of Woundkair, not employees of Medica-Rents, were responsible for any direct marketing to potential purchasers of Medica-Rents' Medicare products, then the court's holding may have been different.[53]

In sum, the court's holdings in *Modern Medical*, *Med. Dev. Network Inc.*, and *Woundkair* were clear: the "recommending purchasing, leasing, or ordering" provision of the AKS criminalizes "broker-style" arrangements even if they do not directly involve physician referrals.

Unfair Competition

Finally, at least one court, in *People of California v. Duz-Mor Diagnostic Laboratory, Inc.*,[54] has concluded that broker-style marketing arrangements that violate state anti-kickback laws also implicate state unfair competition laws.

In *Duz-Mor*, a case which did not involve the AKS but analyzed an almost identical California criminal statute, California's Welfare and Institution's Code,[55] the California Attorney General's Office alleged that Duz-Mor, a clinical laboratory, violated California's Unfair Competition Act[56] by engaging in unfair and illegal practices, *i.e.*, Duz-Mor's commission payments to an independent marketing contractor in contravention of California's Welfare and Institution's Code.[57] The parties disputed these issues at trial and the trial court concluded that Duz-Mor did not violate the Unfair Competition Act by paying commissions to the marketing entity.

On appeal, however, the court found that the commission payments were unquestionably "remuneration," reasoning that, even though the marketing company did not "direct a patient to a laboratory in a way that a doctor might refer a patient to a laboratory, or a lawyer might refer a client to a lawyer with a relevant specialty," the statute "encompasses not just referrals of patients to doctors," including "a wide range of conduct relating to payments which result in an individual receiving services paid for by Medi-Cal."[58] In fact, the court in *Duz-Mor* stressed that "a person of common intelligence would understand that the statute prohibits payment of a commission to someone who arranges, through marketing activities, for services to be furnished to Medi-Cal beneficiaries."[59]

Thus, broadly applied, *Duz-Mor* set the stage for additional unfair competition claims based on marketing activities that violate either state anti-kickback laws or the federal AKS.

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Presently Unresolved Issues

Standing alone, or in combination, *Miles*, *Duz-Mor,* OIG advisory opinions, and court decisions nullifying illegal contracts support different civil and criminal theories of liability for violations of this largely ignored provision of the AKS. Despite this body of case law, in practice the circumstances under which an individual or corporate defendant might violate the "recommending purchasing, leasing, or ordering" provision of the AKS remain unsettled.

Criminal Prosecutions

The fact that the Fifth Circuit's footnote in *Miles* might be the most cogent analysis of this provision of the AKS in the context of a federal criminal prosecution is baffling.[60] Indeed, criminal prosecution of AKS violations involving the type of "broker-style" marketing arrangements highlighted in *Duz-Mor*[61] merit additional government scrutiny, since such arrangements directly contribute to government waste. However, courts have not had ample, if any, opportunities to interpret the "recommending purchasing, leasing, or ordering" provision of the AKS in the context of a criminal prosecution.

Further, neither *Miles* nor other federal courts have decided other significant questions that may fundamentally impact the outcome of an AKS prosecution based on this provision of the AKS. For instance, courts have not decided whether and to what extent a defendant may raise an affirmative defense to an allegation that it violated the "recommending purchasing, leasing, or ordering" provision of the AKS by raising the employee exception[62] or, alternatively, by asserting that the arrangement complies with the personal services and management safe harbor[63] because the' "aggregate compensation" was set in advance.

Despite this lack of case law, the judicial analysis of whether and when a defendant might raise an affirmative defense[64] or an advice of counsel defense[65] to a violation of the second provision of the AKS should be substantially similar to the analysis of whether and when a defendant may raise such defenses to a violation of the companion provision of the AKS.

Another critical question left unanswered by federal district courts relates to the application of the "one purpose" rule. Because federal courts hold that a violation of the AKS occurs if at least one purpose of the remuneration is to induce or reward future *referrals*,[66] will a violation of the second provision of the AKS occur when at least one purpose of the remuneration is to induce or reward a person for recommending the purchase, lease or ordering of an item or service payable by Medicare or Medicaid?

Lastly, questions abound in the pre-indictment context. During pre-indictment negotiations how might a prosecutor respond to the argument that no charges should be filed based on the absence of some, or all, of the six "suspect characteristics" identified by the OIG which pose substantial risks of fraud and abuse? While a defendant might not be entitled to a jury instruction at trial which incorporates those six characteristics identified by the OIG in its advisory opinions discussed above, counsel may certainly emphasize the significance of those characteristics in order to convince a U.S. Attorney's Office to decline prosecution for a violation of this provision of the AKS.

Qui Tam Actions

While there are a limited number of federal criminal cases addressing the application of the "recommending purchasing, leasing, or ordering" provision of the AKS, there are even fewer, if any, reported federal decisions which address whether a relator may file a *qui tam* action premised on an ancillary violation of the "recommending purchasing, leasing, or ordering" provision of the AKS. It is, however, black letter law that, under the FCA, any "person" who presents or causes to be presented[67] a false or fraudulent claim for payment to Medicare or Medicaid that actually knows the claim is false,[68] deliberately ignores the claim's falsity,[69] or acts in reckless disregard of the claim's falsity[70] may be liable for statutory penalties and treble damages.[71]

Courts have also consistently held that a relator may bring a *qui tam* action based on a violation of the AKS.[72] In fact, "[t]hanks to one of the lesser known provisions of the Patient Protection Affordable Care Act (PPACA)...'a claim for payment that includes items or services resulting from a violation of the Anti-Kickback Statute constitutes a false or fraudulent claim for purposes' of the FCA regardless of whether other criteria, like certification, are satisfied."[73]

Relatedly, a common theory of FCA liability is referred to as implied false certification.[74] Under this theory, defendants present false claims to Medicare when they falsely certify compliance with the AKS, a statute upon which the government conditions payment.[75] Accordingly, a violation of the "recommending purchasing, leasing, or ordering" provision of the AKS seems to support an implied false certification theory of liability.[76]

In light of the above authorities, the FCA appears to be an ideal vehicle for prosecuting individuals or organizations when they submit claims for payment to the government in violation of the "recommending purchasing, leasing, or ordering" provision of the AKS. To this end, there is also

no reason to believe that courts would treat relators any differently, or review a *qui tam* action under a separate, more stringent, standard, simply because the action was based on a violation of the second provision of the AKS.

Reverse False Claims

Under these circumstances, relators (and the government) might also seriously consider the benefits of pleading a violation of the "reverse" false claims provision of the FCA.

The "reverse" false claims provision of the FCA makes it unlawful to knowingly conceal or knowingly and improperly avoid or decrease an "obligation" to pay money or property to the government.[77] An "obligation" specifically includes an "established duty arising from…the retention of an overpayment,"[78] which is defined as "any funds that a person receives or retains to which they are not entitled after applicable reconciliation."[79] Because there is a statutory requirement to report and return any overpayment retained by a person no more than 60 days after the date on which it was identified,[80] the failure to do so qualifies as an "obligation" arising from the retention of an overpayment under the FCA.[81]

With this in mind, consider the application of a reverse false claim theory to the marketing arrangement between the home health company and Premier (the marketing company) in *Miles*, assuming *arguendo* that the home health company and Premier had received funds based on Medicare business generated through their marketing arrangement in violation of the second provision of the AKS. Both entities would have received funds to which they were not entitled,[82] since "the government does not get what it bargained for when a defendant is paid by CMS for services that are tainted by a kickback."[83] Likewise, under this scenario, once the home health care company and Premier "identified"[84] these overpayments, they would have been required to report or return those overpayments to their local Medicare Administrative Contractor ("MAC") within the allotted time frame (60 days).[85] And, if they failed to do so, then such conduct might be actionable under the FCA for improperly avoiding or concealing an "obligation" to pay money to the U.S. government,[86] *i.e.* the established duty arising from the retention of an overpayment for more than 60 days."[87]

Accordingly, this hypothetical scenario demonstrates how it might provide relators and the government with the legal authority for collecting ill-gotten gains derived from abusive marketing arrangements when those gains are not timely reported and repaid.

Policy Concerns Explaining the Shortage of Civil and Criminal Cases

So, why are there so few, if any, criminal and civil prosecutions premised on this provision of the AKS? After all, prosecutors, relators, and plaintiffs are aware (or should be aware) of the existence of the "recommending purchasing, leasing, or ordering" provision, and thus, collective ignorance very likely cannot be the driving force behind the shortage of federal jurisprudence. Instead, there are policy concerns that have likely caused prosecutors and plaintiffs to ignore, overlook, or under-value the "recommending purchasing, leasing, or ordering" provision of the AKS.

Substantial Federal Interest and Non-Criminal Alternatives

Assistant U.S. Attorneys must critically evaluate each prosecution, including AKS prosecutions, to ensure that it serves a substantial federal interest.[88] In deciding whether a substantial federal interest exists, prosecutors focus on a variety of factors, including federal law enforcement priorities, the nature and seriousness of the offense, the deterrent effect of the prosecution, and the person's culpability in connection with the offense.[89] Prosecution should also be declined whenever there is an adequate non-criminal alternative to prosecution that "can be expected to provide an effective substitute for criminal prosecution."[90]

Applying these principles of federal prosecution, would the prosecution of a marketing or consulting firm, similar to the firms in *Miles* or *Modern Medical*, for receiving commissions in return for marketing activities that indirectly target Medicare or Medicaid beneficiaries, serve a substantial federal interest? The OIG may impose one of several non-criminal alternatives against individuals or organizations for violations of the AKS. For instance, the OIG may assess a civil monetary penalty against a provider or may exclude a provider from participating in a federal or state healthcare program for a period of years.[91] Accordingly, federal prosecutors may be more willing to decline prosecution especially where, as here, there appear to be several adequate non-criminal alternatives to criminal prosecution.

Bigger Fish to Fry

Understandably, the Department of Justice ("DOJ") Criminal Division may view a criminal prosecution for a technical violation of the AKS as an unnecessary diversion of valuable government resources. After all, the DOJ has bigger fish to fry. In fact, in May of 2015, at the Annual American Bar Association Health Care Fraud Conference, Assistant Attorney General Leslie Caldwell reinforced that the DOJ is not interested in pursuing technical violations and instead continues to focus more aggressively on corrupt medical professionals and fraud that compromises patient safety.[92] Joyce Branda, the Deputy Assistant Attorney General, reiterated this point at the conference, underscoring that one of the DOJ's chief priorities is fraud which endangers patient safety.[93]

For example, the DOJ is currently prosecuting cardiologists based on

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allegations that they implanted stents in patient's hearts for extra Medicare dollars.[94] One oncologist in Detroit was recently sentenced to 45 years in prison for falsely misdiagnosing patients with cancer to line his pockets.[95] A chief executive officer of a hospital in Chicago was convicted of conspiring with other corporate executives at the hospital and patient recruiters to engage in a multi-year kickback scheme which increased the number of patients receiving tracheotomies and was surreptitiously recorded stating that "they are the biggest money maker."[96] A spinal surgeon pleaded guilty to receiving kickbacks from a medical device company as compensation for recommending that the hospital purchase more spinal implants from that company in order to implant as many spinal implants in patients as possible.[97] And a medical device company in Minnesota allegedly deployed a nationwide campaign to deceive doctors about the utility of its varicose vein technology used primarily on elderly patients to remove varicose veins.[98] Undeniably, all of the above prosecutions directly implicate patient safety.

Convincing Juries

An AKS prosecution based on the failure to meet a safe harbor or statutory exception may also be susceptible to jury nullification for two reasons. First, jurors may repudiate the notion that a commission-based marketing arrangement amounts to fraud, especially since sales representatives in dozens of industries – real estate, retail, finance, etc. – are heavily driven by commissions. Second, jurors may get overwhelmed by jury instructions and testimony concerning regulatory safe harbors and conduct which, to lay persons, is widely accepted in many industries. Third, prosecutions targeting marketing activities under the "recommending purchasing, leasing, or ordering" provision of the AKS might be viewed as criminalizing freedom of speech, especially if there is no allegation that the speech is deceptive or misleading.

Countervailing Policy Concerns?

There are several countervailing policy concerns that support the prosecution of individuals and corporate entities for violations of this second provision of the AKS using the different civil and criminal theories of liability discussed herein. Further, the risk of prosecutorial overreaching or the lack of fair warning is marginal, at best, in the context of these prosecutions. The AKS contains well-known and adequate safeguards against prosecutions resulting from violations caused by a mistake, oversight, or carelessness, including the AKS' *mens rea* requirement that an act be done "willfully."[99] Similarly, under the FCA, there are two heightened standards: a plaintiff-whistleblower alleging an AKS violation as the predicate act for the FCA violation must plead fraud with particularity[100] and must prove that the claim made was "knowingly" false or fraudulent.[101]

First, healthcare organizations that market their services through independent consultants who are compensated entirely based on the volume of sales engage in unfair competition to the detriment of their law-abiding rivals. In fact, one of the main reasons for deploying a sales force completely comprised of independent contractors is to avoid the liabilities, costs and risks associated with a bona fide employer-employee relationship, including but not limited to payment of employment taxes, liability for tortious conduct, or providing healthcare and other benefits.

Under this framework, some of the accountability concerns emphasized in OIG advisory opinions are present.[102] Consider the following example: a medical device company and/or medical equipment and supply company may contract with an LLC and that LLC may then enter into a service contract or management agreement with another LLC for the sole purpose of attracting more sales persons (who will then form individual LLCs and recruit their own salespeople) to market the particular devices or equipment in a sales territory. In this context, who controls whom and to whom are they accountable? How is the medical device company monitoring this proliferation of individual LLCs formed to market its services? How, and by whom, are the individual sales representatives trained? Are they required to complete regular compliance training? Are the sales representatives required to have some minimum level of experience with healthcare (e.g. pharmaceutical sales, etc.) or is anyone eligible for these sales positions?

Second, while sales representatives, consultants, or promoters cannot legally "refer" a patient,[103] repeated interaction with physicians, specialists, and their staff is all done in furtherance of obtaining a referral, since a representative is paid based on the volume of the patients referred by a physician. For instance, physicians and their staff are often unfamiliar with the utility of the product or service being promoted or how to properly use it, and therefore, heavily rely on the advice of the sales representatives marketing those products or services in their offices.

Third, although physicians must strictly adhere to their professional and ethical obligations and must only order services or items which are reasonable and medically necessary, there is an undeniable built-in financial incentive for sales and marketing professionals to substantially

influence or interfere with physician decision-making,

Fourth, the Centers for Medicaid & Medicare Services ("CMS") and the federal healthcare programs do not receive the benefit of the bargain – even if a physician authorizes the service, item, or good – when CMS pays for services, items, or goods for Medicare and Medicaid beneficiaries which are tainted by arrangements that violate the AKS.[104] Courts might conclude that the law does not demand *perfect* adherence to complex or overly technical, evolving regulations,[105] but sales and marketing arrangements should not intentionally violate conditions of payment.

Conclusion: Prosecute Where Appropriate

The government has not targeted violations of this provision of the AKS as a top priority, perhaps because of the egregiousness of some of the other healthcare fraud prosecutions nationwide and the existence of adequate non-criminal alternatives to combat some of the sales and marketing arrangements which violate this provision. However, where appropriate, relators, plaintiffs, and assistant U.S. Attorneys should consider prosecution of individuals and organizations under the legal theories discussed in this Article to deter sales and marketing activities which run afoul of the largely forgotten provision of the AKS.

Andrew S. Feldman is the managing member of Feldman Firm PLLC in Miami, Florida where his practice focuses on representing healthcare providers in government investigations targeting healthcare fraud and abuse. Mr. Feldman also represents corporate executives and professionals accused of or under investigation for securities violations and tax violations. Mr. Feldman is a frequent speaker on white collar criminal and healthcare fraud and abuse issues. He may be reached at *afeldman@feldmanpllc.com*.

Endnotes

1 42 U.S.C. § 1320a-7b(b)(1)(A), § 1320a-7b(b)(2)(A).

2 42 U.S.C. § 1320a-7b(b)(1)(B), § 1320a-7b(b)(2)(B).

3 *See* 56 Fed. Reg. 35974 (July 29, 1991).

4 *Id.*

5 *Id.*

6 The AKS itself sets forth an exception for bona fide employees, so "remuneration" received by bona fide employees is protected "remuneration" pursuant to 42 U.S.C. § 1320a-7b(b)(3)(B). Very similarly, there is a regulatory safe harbor protecting "remuneration" paid by an employer to a bona fide employee pursuant to an employment agreement. *See* 42 C.F.R. § 1001.952(i). In addition to the protections afforded to employers and employees, the personal services and management safe harbor protects "remuneration" paid to an independent contractor or remuneration paid pursuant to an agreement between two arms-length parties provided that *seven* (7) requirements are met. Significantly, one of the most often overlooked requirements of this safe harbor, which is especially relevant to a determination of how compensation will be paid in exchange for the performance of sales and marketing services, is that the *aggregate* compensation received must be set in advance. *See* 42 C.F.R. § 1001.952(d).

7 42 C.F.R. § 1001.952(d).

8 *Id.*

9 *United States v. Greber,* 760 F.2d 68, 69 (3rd Cir. 1985) (Under the "one purpose" test, if one purpose of the payment was to induce future referrals, the Medicare statute has been violated.). This test has also been adopted by the Fifth, Ninth, and Tenth Circuits. *See 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. McClatchey*, 217 F.3d 823 (10th Cir. 2000) (reaff'd.), *United States v. LaHue*, 261 F.3d 993 (10th Cir. 2001).

10 *United States v. Earnest Gibson III, et al.*, No. CR-12-600 (S.D. Texas October 13, 2014) (Jury Instructions). The AKS' "willfully" requirement does not require the government to prove that a defendant knew that he violated the AKS, but it demands proof of a defendant's knowledge that his conduct violated some law. *United States v. Jain,* 993 F.3d 436, 441 (8th Cir. 1996) ("Both the plain language of that statute, and respect for the traditional principle that ignorance of the law is no defense, suggest that a heightened *mens rea* standard should only require proof that [defendant] knew that his conduct was wrongful, rather than proof that he knew it violated 'a known legal duty.'"); *United States v. Starks,* 157 F.3d 833, 838 (11th Cir. 1998) (approving the court's jury instructions on "willfully" which required the jurors to find that the defendant acted with "specific intent to do something that the law forbids," and noting that the "the Anti-Kickback statute does not constitute a special exception. Section 1320a-7b is not a highly technical tax or financial regulation that poses a danger of ensnaring persons engaged in apparently innocent conduct."); *see also United States v. Ctr. for Diagnostic Imaging, Inc.*, 787 F. Supp. 2d 1213, 1218 (W.D. Wash. 2011) (*quoting Klaczak v. Consol. Med. Transp.*, 458 F. Supp. 2d 622, 678 (N.D. Ill. 2006)); *see also United States v. Mathur*, 2012 WL 4742833 (D. Nev. Sept. 13, 2012)(D. Nev. Oct. 3, 2012) ("Thus, the Patient Protection and Affordable Care Act (PPACA) has not removed a specific intent requirement from the Anti–Kickback Act as [defendant] claims. In order to prove a violation of the Anti–Kickback Act, the government must still show that a criminal defendant acted 'knowingly and willingly' in offering or paying remunerations in exchange for patient referrals. The PPACA simply clarified that the government is not required to show a criminal defendant specifically knew the Anti–Kickback Act prohibited offering or paying consideration to induce referrals and intended to violate the law.").

11 *United States v. Earnest Gibson III, et al.*, No. CR-12-600 (S.D. Texas October 13, 2014) (Jury Instructions).

12 *United States v. Miles,* 360 F.3d 472, 480 (5th Cir. 2004).

13 *Miles,* 360 F.3d at 480.

14 *Miles,* at 480.

15 *Id.* The Court in *Miles* cited several cases analyzing the first provision (referrals) of the AKS, noting that in those cases, the sales representative essentially stepped into the shoes of the physician based on the representative's substantial influence in the decision-making process. *United States v. Polin,* 194 F.3d 863, 865-67 (7th Cir. 1999) (finding that a pacemaker monitoring service that made payments to a pacemaker sales representative based on the number of patients that he signed up with the service violated the AKS, reasoning that the salesman's substantial responsibilities and direct contact with patients amounted to referrals); *see also United States v. Vernon,* 2013 WL 3835831 (11th Cir. July 26, 2013) (finding that sales representatives previously employed at clinics treating hemophiliacs who were paid based on the number of patients that they recruited to receive treatment from a specialty pharmacy dispensing drugs for the treatment of hemophilia was a violation of the AKS since they were essentially referring patients of the clinic to the specialty pharmacy); *United States v. St. Junius,* 739 F.3d 193 (5th Cir. 2013) (affirming the AKS conviction of defendants who received 10% commission payments as independent contractors for each patient they referred to defendant durable medical equipment (DME) supplier, reasoning that defendants actively recruited patients from home health care companies where they worked part-time to use the services of defendant DME supplier); *see also United States v. Turner,* No. 12-20707 (5th Cir. April 2, 2014) (affirming defendant's convictions, including defendant's conviction to violate the AKS for referring Medicare beneficiaries to DME suppliers in exchange for a $300 payment per beneficiary).

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16 *Miles*, at 480.

17 *Id.*

18 *Id.*

19 *United States v. Carroll*, 320 F. Supp. 2d 748, 755-56 (S.D. Ill. 2004) (denying defendants' motion to dismiss indictment alleging a violation of 42 U.S.C. § 1320a-7b(b)(2)(B) when defendants offered free medical supplies to distributor of durable medical equipment to induce the distributor to purchase, lease, or order additional medical supplies from defendants). Notably, the court also rejected defendants' argument that the discount safe-harbor of the AKS protected the subject marketing arrangement.

20 *United States v. Carroll, et al*, No. 03-CR-30195 (S.D. Ill. Sept. 19, 2003) (DE-1).

21 *Carroll*, 320 F. Supp. 2d at 753-54. The court rejected defendants' argument in their motion to dismiss the indictment on the grounds that the discount safe harbor of the AKS protected the subject marketing arrangement, even though defendants attached affidavits from one of the "principal authors" of the initial AKS safe harbors.

22 *See* Plea Agreement in *United States v. Brian Denny*, No. 03-30193 (S.D. Ill. Jan. 7, 2005) DE-58 at 4-5; *see* Plea Agreement in *United States v. Jo Ann Carroll*, No. 03-30193 (S.D. Ill. Jan. 7, 2005), DE-54 at 4-5.

23 *See* Plea Agreement in *United States v. Brian Denny*, No. 03-30193 (S.D. Ill. Jan. 7, 2005) (DE-58 at 4-5); *see* Plea Agreement in *United States v. Jo Ann Carroll*, No. 03-30193 (S.D. Ill. Jan. 7, 2005), (DE-54 at 4-5).

24 *United States v. Geffrey Yielding*, No. 08-CR-00213 (E.D. Ark. February 4, 2009) (DE-37).

25 *United States v. Terrero, et al*, No. 12-CR-20265 (S.D. Fla. December 11, 2012) (DE-231).

26 *United States v. Terrero, et al*, No. 12-CR-20265 (S.D. Fla. December 11, 2012), (DE-470 at pages 15-16).

27 *See United States v. Novak*, Case No. 13-CR-00312 (S.D. Ill. June 30, 2014)(employee statutory exception is an affirmative defense that must be proved at trial); *United States v. Job*, 387 Fed. Appx. 445, 458 (5th Cir. 2010) (same).

28 Courts generally conclude that the arrangement violates the AKS if a *single purpose* of the arrangement is to induce or reward referrals. *See 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. McClatchey*, 217 F.3d 823 (10th Cir. 2000) (reaff'd.,) *United States v. LaHue*, 261 F.3d 993 (10th Cir. 2001).

29 *See* OIG Advisory Opinion 03-08 (finding that the per patient fees posed high risk of fraud and abuse, noting that "[p]er patient," "per click," "per order," and similar payment arrangements with parties in a position, directly or indirectly, to refer or recommend an item or service payable by a federal healthcare program are disfavored under the AKS. The principal concern is that such arrangements promote overutilization and, in circumstances like those here, unnecessarily lengthy stays); OIG Advisory Opinion 98-1 (percentage compensation arrangement posed a risk of fraud and abuse that precluded a favorable advisory opinion and noting that "[p]ercentage compensation arrangements are potentially abusive...because they provide financial incentives that may encourage overutilization of items and services and may increase program costs"); OIG Advisory Opinion 98-4 (finding that arrangement to market services of clinic whereby marketing company was paid on a percentage basis was problematic); OIG Advisory Opinion 10-23 (per-test marketing fees paid by hospital to a supplier of sleep disorder testing to market the hospital's sleep testing facility posed a high risk of fraud and abuse since "[m]arketing 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" and "supplier receives a fee each time its marketing efforts are successful"); *But See* OIG Advisory Opinion 10-24 (marketing fee for services provided by a sleep testing facility to hospital posed a low risk of fraud and abuse where aggregate amount of fee was set in advance and appeared to be commensurate with fair market value); OIG Advisory Opinion 99-8 (finding that arrangement to pay fixed fee to podiatrists marketing shoe store's products posed a low risk of fraud and abuse, noting that the shoe store does not sell products or provide services reimbursable by any federal healthcare program, the Arrangement involves no explicit arranging for or recommending of any good, facility, service, or item payable by a federal healthcare program, no specific podiatric services are promoted or marketed and while it involves direct patient contact, the Arrangement is not targeted at federal healthcare program beneficiaries.); OIG Advisory Opinion 99-3 (finding that proposed arrangement to pay sales agents of DME supplier a 20% commission for marketing equipment and supplies to skilled nursing facilities ("SNFs") did not pose an unreasonably high risk of fraud and abuse since supplies were not separately reimbursable by federal or state healthcare programs and the cost to SNFs of purchasing the mattresses will be an expense to the SNFs that will reduce its profit under the prospective payment system).

30 *See* OIG Advisory Opinion 98-10.

31 *Id.*

32 *Id.*

33 *Id.* DRGs, or "diagnostic related groups" is a classification system by which hospitals are paid a flat rate for inpatient care.

34 *Id.*

35 *Id.*

36 *Id.*

37 *Id.*

38 *See Id.* at note 22.

39 *Pennington v. Didrickson*, 22 F.3d 1376, 1383 (7th Cir. 1994) (noting that courts have an "obligation to defer to the interpretation of the agency whenever that interpretation can be said to embody a deliberate and considered interpretation of legislative intent"). In fact, no agency is bound to OIG opinions other than HHS. *See* 42 C.F.R. §§ 1008.1, 1008.59; *see also* 42 U.S.C. § 1320a-7d(b).

40 *See, e.g., Joint Technology Inc. v. Weaver*, 2013 WL 257075 (W.D. Okla. Jan. 23, 2013) (contract violated the AKS when a DME distributor entered into a contract with sales representative who received commissions from the distributor based on the volume of DME sold to medical providers and health clinics. DME distributor later argued that the sales representative breached their contract); *Med. Dev. Network, Inc. v. Prof'l Respiratory Care/Home Med. Equip. Servs.*, 673 So. 2d 565, 566-67 (Fla. Dist. Ct. App. 1996) (contract violated the AKS when a DME supplier agreed to pay a marketing firm a percentage of all business developed by the marketing of supplier's durable medical supplies to clients, noting 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"); *Modern Medical Laboratory v. Smith-Kline Beecham, Inc.*, 1994 WL 449281 at *3-4 (N.D. Ill. 1994) (finding that contract violated the AKS when two clinical labs entered into a contract whereby a division of one clinical lab would market, manage, and operate the other clinical lab's business and facilities in exchange for 90% of the revenue generated from that clinical lab's customers and territory, and noting that the AKS "prohibits receiving remuneration in return for arranging for the purchasing of any Medicaid-reimbursable service… it criminalizes broker-style arrangements whereby one entity receives remuneration for placing business with another entity….It is irrelevant that a physician made the initial decision to purchase certain testing services"); *Zimmer Inc. v. Nu-Tech Medical*, 54 F. Supp. 2d 850 (N.D. Ind. 1999) (granting a motion for declaratory judgment that a previous contract was void for illegality because it violated the AKS when a subsidiary of a manufacturer of orthopedics products entered into an agreement with a medical supplier whereby supplier received a percentage of the business developed from sales of the orthopedic products based on the volume of products sold.).

41 *Modern Medical Laboratory v. Smith-Kline Beecham, Inc.*, 1994 WL 449281 at *3-4 (N.D. Ill. 1994).

42 *Modern Medical Laboratory*, at *3.

43 *Id.* at *3.

44 *Med. Dev. Network Inc. v. Prof'l Respiratory Care/Home Med. Equip. Servs.*, 673 So. 2d 565, 566 (Fla. 3rd DCA 1996).

45 *Med. Dev. Network Inc.*, 673 So. 2d at 566.

46 *Med. Dev. Network Inc.*, at 566.

47 *Woundkair Concepts, Inc. v. Medica-Rents,*

Co., Ltd., No. 02-10-00349 (Tex. App. 2d. March 22, 2012).

48 *Woundkair Concepts, Inc. v. Medica-Rents, Co., Ltd.*, No. 02-10-00349, at page 5.

49 *Id.* at page 5.

50 *Id.* at page 6.

51 *Id.* at page 7. The court also did not address the issue of whether the bona fide employee safe harbor applied to the marketing arrangement because it found that Medica-Rents failed to establish illegality as a matter of law.

52 *Id.* at pages 5-7.

53 *Id.*

54 *People of California v. Duz-Mor Diagnostic Laboratory, Inc.*, 80 Cal. Rptr. 2d 419, 429-30 (Cal. App. 2d 1998).

55 *See* California Welfare and Institutions Code § 14107.2(b). The pertinent section of California's Welfare and Institution's Code is almost identical to the "recommending purchasing" provision of the AKS because it expressly prohibits any person from offering or paying any remuneration in exchange for recommending the purchasing of any goods, facility, service, or merchandise for which payment may be made by Medi-Cal.

56 *See* California Business and Professions Code, § 17200.

57 *See* California Welfare and Institutions Code § 14107.2(b).

58 *Duz-Mor Diagnostic Laboratory, Inc.*, 80 Cal. Rptr. 2d at 429-30.

59 *Duz-Mor Diagnostic Laboratory, Inc.*, at 429-30.

60 *Miles*, at 480.

61 *Duz-Mor Diagnostic Laboratory, Inc.*, at 429-30.

62 *United States v. Novak*, Case No. 13-CR-00312 (S.D. Ill. June 30, 2014) (employee statutory exception is an affirmative defense that must be proved at trial).

63 *United States ex rel. Kosenske v. Carlisle HMA, Inc.*, 554 F. 3d 88 (3d. Cir. 2009) (finding that the hospital failed to carry its burden of showing that the personal service exception applied because there was no written contract governing the services provided and there was no written agreement specifying compensation terms).

64 *United States v. Job*, 387 Fed. Appx. 445, 458 (5th Cir. 2010) (emphasizing that defendant was not entitled to raise an affirmative defense of the employee exception to the AKS without first laying a minimal evidentiary foundation for that defense); *United States v. Novak*, Case No. 13-CR-00312 (June 30, 2014) (noting that defendant's invocation of the employee exception as an affirmative defense to the AKS in a pre-trial motion to dismiss the indictment was premature because "for better or for worse there is no such thing as a motion for summary judgment in a criminal case"); *see also United States v. Turner*, No. 12-20707 (5th Cir. April 2, 2014) at page 5 (finding that defendant was not entitled to an employee safe harbor instruction since she had not adduced any facts which would entitle her to such a defense); *United States v. Robinson*, 505 F. App'x 385, 387-88 (5th Cir. 2013) (defendants were not entitled to safe harbor defense where, among other things, they were paid a fee or commission for Medicare beneficiary referrals; they did not receive regular paychecks, only referral payments; they received no training or direction from the alleged employer; they obtained their own leads and sources for referrals; and they were not required to keep regular office hours); *see also United States v. Chris Vernon*, No. 11-CR-00012 (S.D. Ala. February 9, 2012) (DE-543 at 5-6), citing *Hosp. Res. Pers. v. United States*, 68 F.3d 421, 427 (11th Cir. 1995) (government objected to defendant's request for a bona fide employee instruction, but also argued that, if the court were to grant such an instruction, the jurors should be entitled to consider all 20 factors outlined by the Internal Revenue Service in its Revenue Ruling regarding determination of who is a bona fide employee).

65 *Vernon*, 723 F. 3d at 1269-70 (emphasizing that to raise an advice of counsel defense, the defendant must adduce facts showing that: he (i) sought the advice of counsel, in good faith (ii) fully disclosed all of the material facts to the attorney for the purpose of securing legal advice and (iii) acted strictly in accordance with the advice of the attorney). In *Vernon*, defendant specifically ignored general counsel's advice regarding potential kickback risks stemming from an arrangement to pay commissions in exchange for referrals and continued paying kickbacks after he solicited an additional opinion from experienced, outside counsel who concluded that the arrangement did not fit within a safe harbor of the AKS. *See also United States v. McClatchey*, 217 F. 3d 823, 832-33 (10th Cir. 2000) (reversing the district court's order granting defendant's motion for judgment of acquittal concluding that no reasonable juror could find defendant deliberately intended to violate the AKS based on the evidence, including an advice of counsel defense, presented at trial); *United States v. Hill*, 643 F.3d 807, 851 (11th Cir. 2011) (explaining the requirements and the evidentiary basis for requesting an advice of counsel instruction and noting that, while it is a "low burden," the defendant must "put forth sufficient evidence to support a proposed instruction.").

66 *Id.* at note 9.

67 *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 544 (1943) (noting that the purpose of the provisions of the FCA extending its coverage to those who "cause [a false claim] to be presented" and to those who "conspire" to obtain payment of such claims is "to reach any person who knowingly assisted in causing the government to pay claims which were grounded in fraud, without regard to whether that person had direct contractual relations with the government.").

68 *See United States ex rel. Drakeford v. Tuomey Health Care Systems*, No. 05-CV-02858 (D. S.C. 2005) (DE-810) (Jury Instructions) (instructing jurors that "actual knowledge" means "affirmative knowledge that claims were false. It means that the defendant knew what it was doing and was aware of the nature of its conduct and did not act through ignorance, mistake, or accident.").

69 *Id.* at DE-810 (instructing jurors that deliberate ignorance is "a person's knowledge of a particular fact may be shown from a deliberate or intentional ignorance or deliberate or intentional blindness to the existence of that fact.").

70 *Id.* at DE-810 (instructing jurors that they find that defendant acted in "reckless disregard" of the claim's truth or falsity if defendant "submits a claim, or causes a claim to be submitted, without properly considering the claim's truth or falsity" and instructing that "[r]eckless disregard is an aggravated form of gross negligence that addresses the refusal to learn of information which an individual, in the exercise of prudent judgment, should have discovered.").

71 31 U.S.C. § 3729(b)(1)(A); *United States ex rel. Owens v. First Kuwait Gen. Trading & Contracting Co.*, 612 F.3d 724, 728 (4th Cir. 2010) ("Congress, however, has made plain its intention that the act not punish honest mistakes or incorrect claims submitted through mere negligence."); *see United States v. Krizek*, 111 F. 3d 934, 942 (D.C. Cir. 1997) (noting that courts have construed the reckless disregard standard under the FCA as "an extreme version of ordinary negligence.").

72 *Wilkins*, 659 F.3d at 314-15 (reversing the district court's order granting defendants' motion to dismiss relator's FCA claim based on predicate violations of the AKS, finding that relator's FCA claim is viable under an implied false certification theory and reasoning that "compliance does not require perfect adherence to regulations which are not prerequisites to payment from the Government. Compliance, however, does require a participant in a federal health care program to refrain from…entering into payment arrangements that violate the AKS, while making claims to the Government under that program"); *United States ex rel. Ruscher v. Omnicare, Inc.*, No. 4:08-cv-3396 (S.D. Tex. June 12, 2014) (DE-147 at 12-13).

73 *United States ex rel. Ruscher v. Omnicare, Inc.*, No. 4:08-cv-3396 (S.D. Tex. June 12, 2014) (DE-147 at 12-13), *quoting* 42 U.S.C. § 1320a-7b(g).

74 *United States ex rel. Wilkins v. United Health Group Inc.*, 659 F.3d 295, 304-05 (3d. Cir. 2011), *quoting Mikes v. Straus*, 274 F.3d 687, 699 (2d Cir. 2001) ("an implied false certification theory of liability is premised 'on the notion that the act of submitting a claim for reimbursement itself implies compliance with the governing federal rules that are a precondition to payment.'").

75 *See United States ex rel. McDonough v. Symphony Diagnostic Services, Inc.*, No. 2:08-CV-114, 2012 WL 628515 at *1 (S.D. Ohio Feb. 27, 2012) (citing 42 U.S.C. § 1320a-7b(b)(1)(A)) (noting that to be eligible for payment under the Medicare program, providers and suppliers must certify that they understand that payments of claims are conditioned on the claims and the underlying transactions complying with applicable laws, including the AKS.)

76 Relators have previously alleged a hodgepodge of implied false certification theories of FCA liability. *See, e.g., United States ex rel. Hutcheson v. Blackstone Med. Inc.*, 647 F. 3d 377, 379 (1st Cir. 2011) ("we reject the argument that, in the absence of an express legal representation or factual misstatement, a claim can only be false or fraudulent if it fails to comply with a precondition of

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payment expressly stated in a statute or regulation"); *See also United States ex rel. Tyson v. Amerigroup Illinois, Inc.*, 488 F. Supp. 2d 719, 727-28 (N.D. Ill. 2007) ("[t]he enrollment forms are claims because they were 'submitted in order to receive payment,' even if payment was not immediate…. Defendants argue that because the enrollment forms do not explicitly demand any particular amount of capitation-based payments, there was insufficient evidence of falsity"); *United States ex rel. Schwedt v. Planning Research Corp.*, 59 F.3d 196, 199 (D.C. Cir. 1995) ("a claim does not need to be an actual invoice"); *United States v. The Health Alliance of Greater Cincinnati*, No. 1:03-cv-0067, 2008 WL 5282139 (S.D. Ohio Dec. 18, 2008) ("Ohio Heart similarly claims the government has not identified any claim upon which an FCA cause of action may be based. However, the Complaint plainly alleges that Ohio Heart submitted CMS-1500 forms to Medicare, and corresponding Medicaid or Tricare forms, even though it knew it was out of compliance with regulations and laws"); *United States v. United Technologies Corp.*, 626 F.3d 313, 319-20 (6th Cir. 2010) (finding that a FCA claim can be based upon false statements about compliance with a contract and noting that "[the parties] do not dispute that the false statements were material to the government's decision to enter into a contract with Pratt....[A]n invoice, which itself does not contain a falsity, may supply the premise for a false claim if submitted in connection with a fraudulently obtained contract"). False statements on cost reports are also actionable under the FCA. *See United States ex rel. Augustine v. Century Health Services Inc.*, 136 F. Supp. 2d 876, 878 (M.D.Tenn.2000). *See also United States v. Rogan*, 459 F. Supp. 2d 692, 717 (N.D. Ill. 2006) ("Medicaid claims submitted to the state are also 'claims' to the federal government under the FCA."). Lack of documentation for cost claims can also state a FCA violation. *See United States ex rel. Davis v. District of Columbia*, 591 F. Supp. 2d 30, 38 (D.D.C. 2008) ("Plaintiff alleges that the cost claim is false because defendants lacked adequate supporting documentation....As plaintiff describes in his Personal Disclosure Statement, he had several meetings with defendants that confirmed the facts forming the basis of this suit. For these reasons, plaintiff has pleaded with sufficient particularity"); *United States ex rel. Thompson v. Columbia/HCA*, 125 F.3d 899, 902 (5th Cir. 1997) (noting that "violations of laws, rules, or regulations alone do not create a cause of action under the FCA....[F]alse certifications of compliance create liability under the FCA when certification is a prerequisite to obtaining a government benefit"); *But see Wilkins*, 659 F. 3d at 306 (limiting FCA theories of liability to express or implied false certification for violation of "regulations" that "was a condition of payment"); *United States ex rel. Swafford v. Borgess Medical Ctr.*, 98 F.Supp.2d 822, 828 (W.D.Mich.2000) *aff'd*, 24 Fed.Appx. 491 (6th Cir. 2001) (internal quotation marks omitted) (noting that technical violations of administrative regulations are not actionable under the FCA "unless the violator knowingly lies to the Government about them"); *Omnicare, Inc.*, No. 4:08-cv-3396 (S.D. Tex. June 12, 2014) (DE-147 at 35) (noting that if the government upon learning of the violations committed by claimant would have declined payment for those claims, then the "implied false certification theory would not unduly expand FCA liability or do violence to the Act's structure, or purpose.").

77 *See* 31 U.S.C. § 3729(a)(1)(G).

78 *See* 31 U.S.C. § 3729(b)(3).

79 *See* 42 U.S.C. § 1320a-7k(d)(4)(B) (defining an overpayment as "any funds that a person receives or retains under Title XVIII or XIX to which the person, after applicable reconciliation, is not entitled.").

80 42 U.S.C. § 1320a-7k(d)(2) ("an overpayment must be reported and returned… by the later of the date which is 60 days after the date on which the overpayment was identified or the date any corresponding cost report is due, if applicable.").

81 42 U.S.C. § 1320a-7k(d)(3).

82 *See* 42 U.S.C. 1320a-7b(b)(1)(B), (b)(2)(B); 31 U.S.C. § 3729(a)(1)(G); *see also Hess*, 317 U.S. at 544 (noting that the FCA extends its coverage to persons who conspire to present false claims and to persons who "cause to be presented" false claims and thus the FCA indicates a "purpose to reach any person who knowingly assisted in causing the government to pay claims which were grounded in fraud, without regard to whether that person had a direct contractual relationship with the government.").

83 *Wilkins*, 659 F.3d at 314.

84 *See* 77 Fed. Reg. 9179, 9187 (February 16, 2012) ("a person has identified an overpayment if the person has actual knowledge of the existence of an overpayment or acts in reckless disregard or deliberate ignorance of the existence of the overpayment.").

85 Whether or not a voluntary disclosure through the OIG's Self-Disclosure Protocol is warranted under these circumstances to suspend the period for returning and reporting an overpayment, as set forth in 42 C.F.R. § 401.305(b)(2)(i), is beyond the scope of this Article. *See* https://oig.hhs.gov/compliance/self-disclosure-info/files/Provider-Self-Disclosure-Protocol.pdf.

86 31 U.S.C. § 3729(a)(1)(G).

87 31 U.S.C. § 3729(b)(3).

88 *See* United States Department of Justice Manual, Section 9.27-230 ("Initiating and Declining Charges – Substantial Federal Interest").

89 *Id.* at Section 9.27-230 ("Initiating and Declining Charges – Substantial Federal Interest").

90 *See* United States Department of Justice Manual, Section 9.27-250 ("Non-Criminal Alternatives to Prosecution").

91 42 C.F.R. § 1003.103. To avoid exclusion, generally providers and others must enter into an onerous Integrity Agreement or Corporate Integrity Agreement for a period of years.

92 *See* Comments of Assistant Attorney General, Department of Justice, Criminal Division, Leslie Caldwell, ABA National Institute for Health Care Fraud and Abuse, May 2015, Miami Beach, Florida.

93 *See* Comments of Deputy Assistant Attorney General, Department of Justice, Civil Division, Joyce Branda, ABA National Institute for Health Care Fraud and Abuse, May 2015, Miami Beach, Florida.

94 *United States v. John Mitchell*, 14-CR-00306-MEF-WC (M.D. Ala. May 21, 2014) (DE-1); *See United States v. Harold Persaud*, 14-CR-00276-PAG (N.D. Ohio Aug. 20, 2014) (DE-1).

95 *See* http://www.justice.gov/usao-edmi/pr/detroit-area-doctor-sentenced-45-years-prison-providing-medically-unnecessary.

96 *United States v. Edward Novak, et al.* 13-CR-00312 (N.D. Ill. March 18, 2014) (DE-231); *see also* http://www.justice.gov/usao-ndil/pr/owner-and-executives-convicted-medicare-referral-kickback-conspiracy-closed-sacred.

97 *See United States v. Reliance Medical Systems, LLC, et al.* 14-CV-06979-DDP-PJW (C.D. Cal. Sept. 8, 2014) (DE-1 at 53-54) (Complaint); *United States v. Aria Sabit*, 14-CR20779-PDB-RSW (E.D. Mich. December 9, 2014) (DE-19) (Indictment).

98 *See* http://www.justice.gov/opa/pr/vascular-solutions-inc-and-its-ceo-charged-selling-unapproved-medical-devices-and-conspiring.

99 *See United States v. Earnest Gibson III, et al.*, No. CR-12-600 (S.D. Texas October 13, 2014) (Jury Instructions). The AKS' "willfully" requirement does not require the government to prove that a defendant knew that he violated the AKS, but it demands proof of a defendant's knowledge that his conduct violated some law); *United States v. Starks*, 157 F.3d 833, 838 (11th Cir. 1998) (approving the court's jury instructions on "willfully" which required the jurors to find that defendant acted with "specific intent to do something that the law forbids.").

100 *See* Federal Rule of Civil Procedure 9(b).

101 *See* 31 U.S.C. § 3729(a).

102 *See* OIG Advisory Opinion 98-10 (other citations omitted) ("because such agents are independent contractors, they are less accountable to the Seller than an employee. For these reasons, this Office has a long-standing concern with independent sales agency arrangements.").

103 *Polin*, 194 F.3d at 865-67 (finding that a pacemaker monitoring service made payments to a pacemaker sales representative based on the number of patients that he signed up with the service violated the AKS, reasoning that the salesman's substantial responsibilities and direct contact with patients amounted to referrals). Thus, the court in *Polin* expressed these same concerns characterizing the sales representative as someone with sufficient involvement to effectively influence the physician's referrals.

104 *Wilkins*, 659 F.3d at 314 (reiterating that the "government does not get what it bargained

for when a defendant is paid by CMS for services that are tainted by a kickback"); *United States ex rel. Bidani v. Lewis*, 264 F. Supp. 2d 612, 615-16 (N.D. Ill. 2003) ("Compliance with the AKS is thus central to the reimbursement plan of Medicare. To state otherwise would be to allow participation and reimbursement for supplies purchased illegally only because the claimant had the luck of not being caught and convicted in the first place. Reimbursing a claimant for the supplies would put the government in the position of funding illegal kickbacks after the fact.").

[105] *Wilkins*, 659 F.3d at 314-15 (noting that "compliance does not require perfect adherence to regulations which are not prerequisites to payment from the Government. Compliance, however, does require a participant in a federal health care program to refrain from…entering into payment arrangements that violate the AKS, while making claims to the Government under that program.").

Chair's Corner

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Vice Chair, will be working diligently to appoint the 2017 EMI planning committee (along with some 300 other appointments they'll be making), looking for the right blend of experience and new ideas, for diversity in all its forms, for Section members with a passion for putting together outstanding programs.

The 2017 committee will then meet in person in July at our annual all-hands leadership meeting to start laying out the framework for next year's program. Almost immediately, the committee will start poring through the proposals submitted by our Interest Groups, Task Forces and members at large, trying to find the right mix of topics to ensure that EMI 2017 covers the issues that are important to our members no matter what their practice settings, client bases or areas of focus may be. This process alone will occupy several weekly conference calls of an hour or more, as the committee selects plenary sessions and breakouts that will simultaneously have broad appeal and offer in-depth knowledge.

But the topics aren't the end of the job. Matching speakers with those topics can be just as demanding. Sometimes a proposal comes in with a "perfect" speaker panel already attached to it. In many cases, though, the planning committee must put in significant work to ensure that speaker panels reflect the diversity of our membership, provide the range of perspectives offered from different practice settings and geographic locales, involve both established speakers and new voices, and meet the "Three Bears" test – not too large, not too small, but just right. At the same time, the planning committee will be working with our Sponsorship Committee to maximize sponsor support, the support that makes these conferences and our other member services economically viable.

And the job isn't over when the agenda is set and the speakers are confirmed. On the eve of a conference, and even after it has begun, there will invariably be issues that arise – the last-minute schedule conflict, the speaker whose flight was canceled, an attendee who encounters a problem. The planning committee members will be active throughout the conference, introducing speakers, helping members find the session they're looking for, making sure that sponsors and guests feel welcome.

EMI is, of course, just an example. Everything described above is also true of our Washington Health Law Summit and Physicians Legal Issues planning committees, and of the joint planning committee for the Antitrust in Healthcare conference we share with the Section of Antitrust and the American Health Lawyers Association. For all of our conferences, our planning committees have two goals: To make sure that our members and attendees have the best, most valuable CLE and networking experience they can have, and to make it look easy.

But it's not easy at all, and the members who do it are just like you – volunteers who have paying jobs and other commitments, family and friends to spend time with, classes to teach and articles to write and, or so I hear, golf to play and vacations to take. So when you're at one of our conferences, take a minute and look for the folks with the "Planning Committee" ribbons on their badges. They're the wizards behind the curtain, whose job is to take months of hard work and magically transform that work into an outstanding program for you. Shake their hands and tell them thanks. Don't be surprised, though if they tell you that thanks aren't necessary, because planning programs is fun.

(And if you'd like to be a part of that fun, let Joyce Hall (jhall@watkinseager.com) or Hilary Young (hyoung@joyounglaw.com) know, so they'll be aware of your interest when they're appointing next year's planning committees. Program planning is one of the most important tasks in the Section, and one of the most enjoyable, as well.)

See you in San Diego. And D.C. And Chicago. See you at the best programs the healthcare bar has to offer, thanks to our planning committees and staff.

— Bill

MEDICAID RATE CHALLENGES BEFORE AND AFTER *ARMSTRONG V. EXCEPTIONAL CHILD CENTER, INC.*

Felicia Y. Sze, Esq.
Hooper Lundy & Bookman, P.C.
San Francisco, CA

David J. Vernon, Esq.
Kelly A. Carroll, Esq.
Hooper, Lundy & Bookman, P.C.
Washington, DC

The Medicaid program is the safety net program for low-income children, their families, individuals with disabilities and the elderly. As a joint state-federal program, the federal government provides matching funds for state expenditures on each Medicaid program. As a result, the ability of the Medicaid programs to serve beneficiaries, especially with respect to provider payment rates, depends upon the fiscal health of the states.

Over the years, and most recently during the Great Recession that began in 2007, due to negatively impacted state finances and motivated by budgetary concerns, some states have reduced provider reimbursement rates despite the impact such reductions may have on beneficiary access. For instance, in 2012, 44 states either reduced or froze Medicaid rates, and 26 did so in 2013.[1] In many instances, the rates have fallen well below the cost for providers to deliver the services to Medicaid beneficiaries, which limits the extent to which providers can economically serve Medicaid beneficiaries.

As a result, providers have filed challenges to the budget-driven reduction of rates in various states. Although other provisions of the Medicaid Act have been utilized, these rate challenges have primarily relied on 42 U.S.C. Section 1396a(a)(30)(A) ("Section 30(A)"), which requires that states choosing to accept federal Medicaid funds must "assure that payments...are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area."[2]

Central to the fight concerning these Section 30(A) lawsuits, however, is under what jurisprudential right can these private suits be brought either in law or equity. Providers and beneficiaries have used two main legal arguments to sue state Medicaid agencies to stop provider reimbursement cuts. The first entails a suit under Section 1983 of the Civil Rights Act ("Section 1983") against state officials, alleging that state actions violate federal law. The second involves the existence of an implied private right of action that allows private actors to request courts to enjoin state actions that are contrary to the federal Constitution or federal statutes.

Armstrong v. Exceptional Child Center, Inc. ("*Armstrong*") is the latest in the line of these Section 30(A) private enforcement cases; however, it might be the last as it arguably has eliminated private enforcement actions under either the Supremacy Clause or directly under Section 30(A).[3] This article discusses the background of Section 30(A) cases, *Armstrong*, and its impact on future rate challenges.[4]

The Boren Amendment, The "Equal Access Provision," and *Wilder*

In 1981, Congress amended 42 U.S.C. Section 1396a(a)(13)(A) in what has been called the "Boren Amendment" to require states to reimburse hospitals at rates that are "reasonable and adequate to meet the costs which must be incurred by efficiently and economically operated facilities."[5] In the same legislation, Section 30(A), which originally required that Medicaid payments not be "in excess of reasonable charges consistent with efficiency, economy, and quality of care," was amended to remove the "in excess of reasonable charges" language.[6]

In amending the Medicaid Act, Congress recognized that "without adequate payment levels, it is simply unrealistic to expect physicians to participate in the [Medicaid] program."[7] Congress intended the Boren Amendment to provide states with more flexibility to determine reimbursement rates, in part by eliminating the requirement that states reimburse providers on a reasonable cost basis.[8] For example, as the Supreme Court of the United States has noted, states had the power to adopt state plans that provided for prospective payments to providers, rather than retrospective payments.[9]

In 1989, Congress further amended Section 30(A) by inserting the "Equal Access Provision" — "and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area" — after the language concerning assuring "that payments are consistent with efficiency, economy, and quality of care[.]"[10] Together, the Boren Amendment and Section 30(A) became the basis for many provider rate challenges.[11] Many of these actions were premised on the enforceability of these provisions of the Medicaid Act as enforceable rights under Section 1983.[12]

In *Wilder v. Virginia Hospital Association*, the Supreme Court held that the Boren Amendment creates a federal right, enforceable by providers in a private cause of action pursuant

to Section 1983, to "have the State adopt rates that it finds are reasonable and adequate rates to meet the costs of an efficient and economical health care provider."[13] Thus, the Supreme Court had determined that providers could challenge a state's Medicaid rate reductions under the Boren Amendment and Section 1983. After *Wilder*, Congress amended the Medicaid Act by repealing the Boren Amendment in 1997.[14]

Gonzaga and Section 1983's Reach

After the repeal of the Boren Amendment, providers continued to try to enforce Section 30(A) under Section 1983. As noted above, Section 1983 generally provides a cause of action where there is a deprivation of a right secured by federal statutes or the Constitution.[15] A plaintiff may sue under Section 1983 unless (1) the statute in question does not create enforceable "rights, privileges, or immunities" within Section 1983's meaning, or (2) Congress has foreclosed such private enforcement of the statute under Section 1983 in the enactment itself.[16] Following *Wilder*, the Supreme Court set forth factors for courts to consider in determining whether a federal statute confers an enforceable right: (1) "Congress must have intended that the provision in question benefits the plaintiff"; (2) "the plaintiff must demonstrate that the right assertedly protected by the statute is not so 'vague and amorphous' that the enforcement would strain judicial competence"; and (3) "the statute must unambiguously impose a binding obligation on the states."[17]

In an attempt to clear up confusion regarding the reach of Section 1983, the Court in *Gonzaga v. Doe* rejected the notion that its jurisprudence permits "anything short of an unambiguously conferred right to support a cause of action brought under § 1983."[18] The Supreme Court emphasized that the primary question is whether Congress intended to create a federal right of action.[19]

Gonzaga significantly altered Section 1983 jurisprudence as it relates to Section 30(A). For example, prior to *Gonzaga*, the First, Seventh and Eighth Circuits held that Section 30(A) provided Medicaid providers with a right enforceable under Section 1983.[20] However, following *Gonzaga*, the First, Second, Fifth, Sixth, Ninth and Tenth Circuits held that Section 30(A) is unenforceable under Section 1983.[21] As explained by the Fifth Circuit in *Equal Access for El Paso, Inc.*, *Gonzaga* forces that court to "abjure the notion that anything short of an unambiguously conferred private individual 'right,' rather than the broader or vaguer 'benefits' or 'interests,' may be enforced under § 1983."[22] The Fifth Circuit, like many other circuits, held that Section 30(A) focused on access in the aggregate and on a systemic basis, "rather than an individualized focus concerned with whether the needs of any particular person or class of recipients have been satisfied."[23] The Fifth Circuit thus held that Section 30(A) failed to confer private rights on Medicaid recipients to enforce the equal access requirement under Section 1983.[24]

The Supremacy Clause

Due to the changing Section 1983 landscape, providers and Medicaid recipients looked for alternative legal mechanisms to enforce Section 30(A). Most notably, providers turned to the Supremacy Clause to bring claims for equitable relief against states.[25] Going back almost two centuries, the Supreme Court held that a federal court that has subject-matter jurisdiction may grant an injunction or writ at the request of an individual who has standing to bring a government official into compliance with federal law.[26] In that case, a federal court issued an injunction prohibiting an Ohio official from executing a state law that was to tax the Bank of the United States.[27] As the Supreme Court explained in a subsequent case, *Davis v. Gray*, it held that a federal court "in a proper case in equity, may enjoin a state officer from executing a state law in conflict with the Constitution or a statute of the United States, when such execution will violate the rights of the complainant."[28] In other words, as early as 1824 the Supreme Court held that there is an implied federal cause of action to enjoin state laws preempted under the Supremacy Clause.[29]

An important example of this implied cause of action was addressed in *Ex parte Young*.[30] In that case, shareholders of a railroad were allowed to seek an injunction preventing the state attorney general from enforcing a state law that set maximum railroad rates.[31] Attorney General Young argued that he was immune from suit under the Eleventh Amendment because he was acting on behalf of the state.[32] Nonetheless, the Supreme Court determined that "[i]f the act which the state attorney general seeks to enforce be a violation of the Federal Constitution, the officer, in proceeding under such enactment, comes into conflict with the superior authority of that Constitution, and he is in that case stripped of his official or representative character and is subjected in his person to the consequences of his individual conduct."[33] Thus, the Supreme Court explained that a federal court had the equitable power to "grant a temporary injunction" against the attorney general.[34] The Court's holding has been interpreted to mean that this implied cause of action exists to enjoin state officials who come into conflict with the Constitution or federal laws.[35]

These principles are by no means relics of a bygone era. The Supreme Court relied upon *Ex parte Young* as recently as 2010 in the *Free Enterprise*

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Fund v. Public Company Accounting Oversight Board case.[36] In *Free Enterprise Fund*, the United States argued that there was no cause of action that existed to challenge federal legislation as unconstitutional under separation of powers principles.[37] In essence, the United States argued that such a challenge should be treated differently from every other constitutional claim for which equitable relief has long been recognized as the proper means for preventing entities from acting unconstitutionally.[38] However, the Court relied on the validity of the equitable principle described in *Ex parte Young* to reject the United States' position.[39]

Underlying the implied cause of action exemplified in the *Ex parte Young* jurisprudence is that this cause of action includes enforcement of the Supremacy Clause's effect of preempting state laws that conflict with federal laws. Moreover, the Supreme Court has even gone so far as to characterize "the availability of prospective relief of the sort awarded in *Ex parte Young* [as giving] life to the Supremacy Clause."[40] On this basis, providers and recipients have alleged an implied cause of action under the Supremacy Clause to continue to challenge provider rate reductions under Section 30(A).

Refusal to Address The Enforceability of Section 30(A) Under the Supremacy Clause

The Supreme Court first considered whether Section 30(A) was enforceable in *Douglas v. Independent Living Center of Southern California, Inc.*, which was the culmination of a series of challenges to rate reductions.[41] In that case, the California legislature sought to cut Medi-Cal fee-for-service reimbursement by ten percent for many types of providers, including physicians, dentists, and pharmacies. A group of providers, beneficiaries and representative associations sued the California Medicaid agency in an attempt to enjoin the cuts on the grounds that, among other things, they violated Section 30(A). The Ninth Circuit, relying on two centuries of precedent allowing private parties to sue state officials for injunctive relief in federal court to challenge state laws under the Supremacy Clause, held that the providers and beneficiaries could sue to enforce Section 30(A) under the Supremacy Clause even if they could not under Section 1983 of the Civil Rights Act.[42] During the pendency of the case below, the Centers for Medicare & Medicaid Services ("CMS") had not yet approved amendments submitted by California to the Medicaid State Plan to implement the rate reduction.

The Supreme Court granted certiorari concerning whether plaintiffs could sue under the Supremacy Clause. However, after the case was briefed and argued before the Court, CMS approved the rate cuts at issue retroactively.[43] Because of the changed circumstances, the Supreme Court did not decide whether a Section 30(A) private action suit could be maintained under the Supremacy Clause.[44] Rather, the Court ruled that the case should be remanded to the Ninth Circuit because the state plan amendments had been approved.[45] The Supreme Court's ruling afforded the Ninth Circuit the opportunity to decide whether the approval of the state plan amendments, including the availability of an Administrative Procedures Act ("APA") claim to challenge the federal approval, would have an impact on the availability of a preemption claim.[46] In vacating and remanding the case to the Ninth Circuit, the Court indicated that the plaintiffs' claim may be brought directly against CMS under the APA.[47] The Supreme Court also stated that "the APA would likely permit respondents to obtain an authoritative judicial determination of their claim."[48] However, although *Douglas* did not explicitly answer the question of whether Section 30(A) could be enforced under the Supremacy Clause, earlier this year the Supreme Court in *Armstrong* clearly determined that it could not.

The Supreme Court's Decision in *Armstrong v. Exceptional Child Center, Inc.*

On March 31, 2015, the Supreme Court significantly diminished the ability of providers to challenge Medicaid rates as inconsistent with Section 30(A) by overturning the Ninth Circuit Court of Appeal's decision in *Exceptional Child Center, Inc. v. Armstrong*[49] ("*Exceptional Child Center, Inc.*").[50] Justice Scalia delivered the majority opinion (Roberts, C.J., Thomas, Breyer and Alito joining) of the Supreme Court on: (1) the background of the case; (2) holding that the Supremacy Clause does not confer a private right of action granting plaintiffs access to the courts; and (3) that providers may not sue in equity to enforce Section 30(A). Justice Scalia further delivered a plurality opinion (Roberts, C.J., Thomas, and Alito joining) that providers may not sue using Section 30(A) as a private right of action. Justice Breyer filed an opinion concurring in this portion of the opinion delivered by Justice Scalia. Justice Sotomayor filed a dissent, in which Justices Kennedy, Ginsburg, and Kagan joined.

In *Exceptional Child Center, Inc.*, the Ninth Circuit sustained the challenge of Medicaid-supported living services providers to Idaho's failure,

for lack of appropriated funds, to adopt significant rate increases that a state-commissioned study had recommended were necessary to substantially reimburse providers for their costs.[51] The Ninth Circuit held that the providers had a right of action under the Supremacy Clause to challenge Idaho's rates as preempted by the Medicaid payment requirements of Section 30(A).[52] The Court held that the existing rates were invalid under *Orthopaedic Hospital v. Belshe*,[53] in which the Ninth Circuit interpreted Section 30(A) to require states to consider costs when modifying rates because the rates failed to substantially reimburse providers for their costs without any justification apart from "purely budgetary reasons."[54]

The Supreme Court granted certiorari as to whether the providers had a right of action under the Supremacy Clause, but denied review on the issue of compliance with the substantive payment requirements of Section 30(A). Oral argument was presented on January 20, 2015.

The majority opinion ruled that the Supremacy Clause itself does not confer a private right of action. By its text,[55] the majority determined that the Supremacy Clause creates a rule of decision, i.e., a rule governing the laws that must be applied by courts, and is not an independent source of rights granting a private right of action.[56] The majority supported this holding by noting the absence of any reference in the historical preratification record of the Constitution that the Supremacy Clause would give affected parties "a constitutional right to enforce federal laws against the States."[57] The majority further supported this ruling by reasoning that, as the Supremacy Clause is found in Article I of the Constitution, an Article that grants broad discretion to Congress, it is suspect that the Constitution would grant such broad discretion while prohibiting Congress from establishing methods of enforcement by necessarily requiring private enforcement under the Supremacy Clause.[58]

The majority acknowledged that the Supreme Court has previously permitted cases for injunctive relief to proceed against state (and federal) officers for violation of federal law. However, the majority explained that these cases are not based on the Supremacy Clause as a private right of action.[59] "What our cases demonstrate is that, 'in a proper case, relief may be given in a court of equity...to prevent an injurious act by a public officer.'"[60]

The majority similarly dismissed the respondents' contention that they could proceed in equity against the state under Section 30(A). Warning that the equitable power of federal courts "is subject to express and implied statutory limitations," the majority found that respondents cannot circumvent Congress's intent to foreclose private enforcement of Section 30(A).[61] The majority cited two aspects of Section 30(A) to support its holding that Congress intended to exclude private enforcement. First, Congress expressly provided a single administrative remedy for "a State's failure to comply with Medicaid's requirements"—"the withholding of Medicaid funds by the Secretary of Health and Human Services."[62] Second, acknowledging that this enforcement provision alone might not preclude equitable relief, the majority reasoned that the enforcement provision would do so "when combined with the judicially unadministrable nature of §30(A)'s text."[63] The majority cited the breadth and lack of specificity of Section 30(A)'s "judgment-laden standard" in support of its holding that Congress intended to confer enforcement of Section 30(A) on the Secretary alone.[64]

The majority acknowledged the dissent's disagreement as to whether Congress intended to preclude private enforcement of Section 30(A). However, the majority found unavailing the dissent's contention that, based on the history of Section 30(A), Congress's failure to *expressly* preclude private enforcement suggests that Congress did not intend to do so.[65] In essence, the majority turns the presumption in favor of judicial review upside down by holding that there must be evidence that Congress intended that private parties would be permitted to sue to enforce a federal law, and that in the absence of such evidence, either in the language of the statute or elsewhere, it would be implied that Congress did not intend to allow private enforcement in court.[66] Moreover, in response to the dissent's complaint that the majority has left the respondents with no options for relief, the majority explained that relief may be sought through the Secretary and expressed doubt that "the Secretary's notice to a State that its compensation scheme is inadequate will be ignored."[67]

The plurality also dismissed the respondents' assertion that the Medicaid Act itself provides for a cause of action. Stating that Section 30(A) "is phrased as a directive to the federal agency charged with approving state Medicaid plans," the plurality explained that Section 30(A) lacks the sort of rights-creating language needed to imply a private right of action.[68] The plurality further explained that Section 30(A) explicitly confers a means of enforcement through the Secretary's withholding of funding, and that this suggests that other means of enforcement, such as a private right of action, are precluded.[69] The plurality continued that, although providers are not intended beneficiaries of the Medicaid agreement, and therefore, unlikely to have a right to sue to enforce the obligations of private contracting parties, even if they were, "modern jurisprudence permitting intended beneficiaries to sue does not generally apply to contracts between a private party and the

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government...much less to contracts between two governments."[70] Thus, the plurality concluded that the Medicaid Act itself does not unambiguously confer a private right of action.[71]

Justice Breyer, concurring in part and concurring in the judgment, did not join the plurality concerning why the Medicaid Act itself does not provide for a private right of action. Instead, Justice Breyer explained that several characteristics of the Medicaid Act "make clear that Congress intended to foreclose respondents from bringing this particular action for injunctive relief."[72]

Specifically, Justice Breyer reasoned that Section 30(A) sets forth a broad and nonspecific federal mandate that applies to something "that administrative agencies are far better suited to...than judges" — the setting of rates.[73] Justice Breyer continued that Section 30(A) "underscores the complexity and nonjudicial nature of the rate-setting task."[74] Although he acknowledged that federal courts are accustomed to reviewing agency rate-setting determinations for reasonableness or constitutionality, Justice Breyer cautioned that, under Section 30(A), states setting the rates makes the result different.[75] As Justice Breyer noted, "[t]o find in the law a basis for courts to engage in such direct rate-setting could set a precedent for allowing other similar actions, potentially resulting in rates set by federal judges...outside the ordinary channel of federal judicial review of agency decisionmaking."[76] Therefore, Justice Breyer did not believe that Congress intended to allow such a situation; however, he did suggest that the power to sue the Secretary under the APA is an adequate form of relief in this complex rate-setting area.[77] Justice Breyer concluded that any difficulty for respondents in prevailing under the APA "is because Congress decided to vest broad discretion in the agency to interpret and to enforce §30(A)" and such difficulty is not a justification for a private right of action.[78]

Dissenting, Justice Sotomayor disagreed that the language of Section 30(A) demonstrates the requisite congressional intent to restrict the equitable authority of the federal courts.[79] The dissenting opinion reasoned that a challenge to governmental action under the Supremacy Clause should not be treated any "'differently than every other constitutional claim' for which 'equitable relief has long been recognized as the proper means for preventing entities from acting unconstitutionally.'"[80] That is, the Court has "long entertained suits in which a party seeks prospective equitable protection from an injurious and preempted state law without regard to whether the federal statute at issue itself provided a right to bring an action," and that this case should be no different.[81]

Citing a distinction between an *Ex parte Young* analysis and the principles concerning whether a statute creates an implied right of action or is enforceable through Section 1983, Justice Sotomayor elaborated that "concluding that Congress has implicitly precluded private enforcement of §30(A)...ignores this critical distinction and threatens the vitality of our *Ex parte Young* jurisprudence."[82] Moreover, the dissenting opinion explained that for *Ex parte Young* not to be applicable, there needs to be a "carefully crafted and intricate remedial scheme for enforcement of §30(A)."[83] However, Justice Sotomayor found no such remedial scheme in the language of Section 30(A), instead reasoning that "§1396c provides no specific procedure that parties actually affected by a State's violation of its statutory obligations may invoke in lieu of *Ex parte Young*."[84]

Further, disagreeing with the notion that the language of Section 30(A) is "judicially unadministrable" and that therefore "Congress must have intended to preclude its enforcement in private suits," Justice Sotomayor asserted that Section 30(A)'s "breadth counsels in favor of interpreting § 30(A) to provide substantial leeway to States, so that only in rare and extreme circumstances could a State actually be held to violate its mandate."[85] Moreover, the dissenting opinion acknowledged that such appropriately made decisions by the states "should be accorded the appropriate deference."[86] Thus, the dissenting opinion asserted that "[g]iven the courts' ability to both respect States' legitimate choices and defer to the federal agency when necessary, [there is] no basis for presuming that Congress believed the Judiciary to be completely incapable of enforcing § 30(A)."[87]

Ultimately, the *Armstrong* decision appears to hold once and for all that providers cannot challenge Medicaid rates as violating Section 30(A), either under Section 1983 or the Supremacy Clause. As such, what tools are left for providers and beneficiaries to ensure equal access under the Medicaid program, and where do stakeholders go from here?

Post-*Armstrong*: What is the Outlook for Medicaid Rate Challenges?

Armstrong significantly limits the ability of providers and Medicaid beneficiaries to challenge Medicaid rate reductions, especially under Section 30(A). As such, *Armstrong* removes one of the few tools that counter-balanced the ability of states to unilaterally reduce provider rates without regard to whether the resulting rates failed to entice sufficient high-quality providers to participate

in Medicaid programs. Moreover, the "federal government lacks the financial, legal, logistical, and practical wherewithal comprehensively to enforce § 30(A) against the states."[88] Indeed, the only weapon in the Secretary of HHS's arsenal — revocation of a state's federal funding, 42 U.S.C. § 1396c — is the administrative equivalent of a nuclear bomb: "[A] funds cutoff is a drastic remedy with injurious consequences to the supposed beneficiaries of the Act."[89] Were the Secretary to revoke funding of a state's Medicaid program for non-compliance with Section 30(A), recipients would lose health coverage altogether, making matters far worse. States know that this "remedy is so destructive to the underlying aid program that it is rarely, if ever, invoked."[90]

However, Medicaid providers may still have limited options to challenge state actions that are in conflict with other provisions of the Medicaid Act. Providers can still enforce Medicaid Act provisions that grant a private right of action on providers under Section 1983 or may continue to seek injunctive relief under the Supremacy Clause for provisions of the Medicaid Act that are not "unadministrable." For example, the District Court for the Southern District of Florida has continued to entertain a rate challenge with respect to preventive children's services under 42 U.S.C. Sections 1396a(a)(8), (a)(10), and (a)(43), which the court has held enforceable under Section 1983.[91] Further, claims to enjoin states from implementing changes to Medicaid programs prior to CMS approval of a State Plan Amendment are likely to continue to be justiciable.[92]

State laws also may limit state Medicaid agencies' ability to reduce rates.[93] As such, providers may utilize state law vehicles, such as state writs of mandate, to force state officials to comply with the Medicaid Act or state laws.[94]

One last avenue that providers and beneficiaries still have to contest rate reductions is the ability to challenge arbitrary and capricious CMS actions under the APA.[95] However, such challenges are often difficult to win, as courts apply a highly deferential standard when reviewing agency action under the APA, especially in a highly complex regulatory program such as Medicaid.[96]

Conclusion

The issue of access in the Medicaid programs continues to be perplexing from the perspective of the federal and state governments, as well as for providers, beneficiaries and other stakeholders. On November 2, 2015, CMS issued its long-awaited final rule implementing Section 30(A). In that final rule, CMS acknowledges that the ruling in *Armstrong* that providers and beneficiaries lack a private right of action under the Supremacy Clause to enforce Section 30(A) "underscores the need for stronger non-judicial processes to ensure access, including stronger processes at both the state and federal levels for developing data on beneficiary access and reviewing the effect on beneficiary access of changes to payment methodologies."[97] Further complicating the ability of Medicaid programs to ensure access to beneficiaries is a seismic shift of Medicaid programs into managed care.[98] CMS has recently proposed regulations that would govern the availability of services, assurances of adequate capacity and services, and network adequacy standards for Medicaid managed care plans.[99]

CMS is in the process of collecting comments as to what standards should be used to measure access and how these standards should be applied to Medicaid fee-for-service programs, managed care programs or to both together.[100] CMS intends to use the comments received to "strengthen the framework for CMS review to ensure that rates meet the requirements of [Section 30(A) of the Act], including requiring access improvement strategies to improve care delivery where there are shortcomings."[101] The establishment of a more transparent and accountable access review and monitoring process may minimize the need for providers and beneficiaries to seek judicial enforcement of Section 30(A).

Felicia Y Sze, Esq., is a partner in the regulatory department of Hooper, Lundy & Bookman, P.C. Ms. Sze is a recognized expert in Medicaid and Medicare reimbursement matters. She advises healthcare providers regarding regulatory compliance and in disputes with managed care entities and government payors. Ms. Sze has also represented healthcare providers on public policy issues, including challenges to the validity of rate reductions or regulations and drafting proposed legislation or rulemaking comments. Ms. Sze also actively defends providers against administrative actions. Her practice areas include state financing of Medicaid programs, administrative citations and penalties, electronic health record incentive programs and audits, and arbitration agreements.

Ms. Sze earned her B.A. in Molecular and Cell Biology/Genetics from the University of California at Berkeley in 1996. She was the 1996 winner of the Kenneth Priestley award for outstanding student leadership and contribution to student welfare. Ms. Sze earned her M.P.H. degree specializing in Community Health Sciences/Health Policy from the University of California at Los Angeles in 1998. After graduating from the University of California at Los Angeles, Ms. Sze served as a Presidential Management Intern for the U.S. Department of Health and Human Services. In this capacity, she acted as the Regional Affairs Specialist to the Regional Director, Region IX.

Ms. Sze received her J.D. from the University of California at Berkeley, Boalt Hall School of Law in 2004. In

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2002, Ms. Sze was awarded the Barbee Legal Research Fellowship for healthcare law. In addition, Ms. Sze served as Research Assistant to Professor Marjorie Shultz for three years, during which time she researched and edited publications related to medical mistakes and racial disparities in health. She can be reached at *fsze@health-law.com*.

David J. Vernon, Esq., worked as a research assistant for the Warren Institute's Health, Economic & Family Security Program on legal issues impacting the creation of safety-net Accountable care Organizations while in law school. He was also a two-time Prosser Prize winner, a member of the Berkeley Technology Law Journal, and an Advocacy Award winner.

Prior to attending law school, Mr. Vernon worked as the research analyst to the President/CEO of the Association of American Medical Colleges, where he published a number of articles in peer-reviewed biomedical journals.

Mr. Vernon received his B.A. degree in Neuroscience and Behavior from Vassar College in 2006, graduating with departmental and general honors. He received his J.D. degree from the University of California, Berkeley School of Law in May 2012, where he was Co-President of the Boalt Healthcare and Biotech Law Society. He can be reached at *dvernon@health-law.com*.

Kelly A. Carroll, Esq., is an associate in the Regulatory Department of the firm's Washington, DC office. Her practice focuses on representing clients in the healthcare and life sciences industries in a wide range of regulatory, transactional and litigation matters, including areas such as reimbursement, HIPAA, health information technology, regulatory compliance, and long term care issues. In addition, she advises states on matters involving federal funding of state healthcare programs and disputes with the Centers for Medicare & Medicaid Services (CMS). She writes and speaks on legal and ethical issues related to healthcare reform, health privacy, clinical research, and Catholic healthcare systems.

Prior to her legal career, Ms. Carroll conducted NIH-funded bioethics research at the University of Pennsylvania and Saint Louis University, and she was awarded a fellowship at the Institute for Ethics of the American Medical Association. Kelly also served as the Executive Managing Editor of *The American Journal of Bioethics*.

Ms. Carroll received a Bachelor of Arts degree in Religion from Haverford College and a Master of Bioethics (MBE) from the University of Pennsylvania. She received her J.D. from Saint Louis University School of Law, where she was the Executive Editor of the Saint Louis University Journal of Health Law & Policy. While in law school, Ms. Carroll worked on healthcare fraud and abuse matters as a legal intern with the U.S. Attorney's Office for the Middle District of Pennsylvania. She also worked in her law school's Mediation Clinic and received a Certificate in Health Law. She can be reached at *kcarroll@health-law.com*.

Endnotes

1 Nat'l Governors Ass'n & Nat'l Ass'n of State Budget Officers, *The Fiscal Survey of States: An Update on State Fiscal Conditions* 58 (2012 & 2013).

2 42 U.S.C. § 1396a(a)(30)(A).

3 135 S.Ct. 1378 (2015).

4 The authors note that CMS finalized the long-awaited rule implementing Section 30(A) on November 2, 2015. (Medicaid Program; Methods for Assuring Access to Covered Medicaid Services; Final Rule, 80 Fed. Reg. 67,576 (Nov. 2, 2015)). At the time this article was submitted for publication, the final rule had not been published in the Federal Register, so this article does not focus on the details of the final rule.

5 Omnibus Budget Reconciliation Act of 1981, Pub. L. 97-35, § 2173, 95 Stat. 808.

6 Omnibus Budget Reconciliation Act of 1981, Pub. L. 97-35, § 2174(a), 95 Stat. 809.

7 *See Wilder v. Virginia Hosp. Ass'n*, 496 U.S. 498, 506 (1990) (discussing H.R. Rep. No. 97-158, Vol. 2, p. 293 (1981); S. Rep. No. 97-139, p. 478 (1981)).

8 *See id.* (discussing H.R. Rep. No. 97-158, Vol. 2, *supra*, at 292-293; S. Rep. No. 96-471, p. 29 (1979)).

9 *See id.* (discussing H.R. Rep. No. 97-158, Vol. 2, *supra*, at 292-293; S. Rep. No. 96-471, p. 29 (1979)).

10 Omnibus Budget Reconciliation Act of 1989, Pub. L. 101-239, § 6402(a), 103 Stat. 2260.

11 *See, e.g., Wilder v. Virginia Hosp. Ass'n*, 496 U.S. 498 (challenge to hospital rates under Boren Amendment); *Arkansas Med. Soc'y, Inc. v. Reynolds*, 6 F.3d 519 (8th Cir. 1993) (Section 30(A) challenge to 20% across-the-board rate reduction for non-institutional providers).

12 Section 1983 provides in relevant part:

"Every person who, under color of any statute, ordinance, regulation, custom, or usage, of any State or Territory or the District of Columbia, subjects or causes to be subjected, any citizen of the United States or other person within the jurisdiction thereof to the deprivation of any rights, privileges, or immunities, secured by the Constitution and laws shall be liable to the party injured in an action at law, suit in equity, or other proper proceeding for redress." 42 U.S.C. § 1983.

13 *See Wilder*, 496 U.S. at 524.

14 Balanced Budget Act of 1997, Pub. L. No. 105-33 § 4712(c), 111 Stat. 509. The Boren Amendment was repealed largely due to a concerted effort by states where they claimed that the Boren Amendment needlessly constrained their ability to institute flexible, cost-effective systems of care under Medicaid and that it imposed significant fiscal demands on the states.

15 *See Wilder*, 496 U.S. at 508.

16 *Id.*

17 *Blessing v. Freestone*, 520 U.S. 329, 340-41 (1997).

18 536 U.S. 273, 283 (2002)

19 *Id.*

20 *See Sanchez v. Johnson*, 416 F.3d 1051, 1058 (9th Cir. 2005) (citing *Visiting Nurse Ass'n*, 93 F.3d at 1005 (1st Cir. 1996); *Methodist Hosps. v. Sullivan*, 91 F.3d 1026, 1029 (7th Cir. 1996); *Arkansas Med. Soc'y, Inc.*, 6 F.3d at 528.)

21 *See Equal Access for El Paso, Inc. v. Hawkins*, 509 F.3d 697, 704 (5th Cir. 2007); *N.Y. Ass'n of Homes & Servs. for the Aging, Inc. v. DeBuono*, 444 F.3d 147 (2d. Cir. 2006), *aff'g sub nom.*; *In re NYAHSA Litigation*, 318 F.Supp.2d 30, 39-40 (N.D.N.Y 2004); *Westside Mothers v. Olszewski*, 454 F.3d 532, 542-43 (6th Cir. 2006); *Mandy R.*

ex rel. R. v. Owens, 464 F.3d 1139, 1148 (10th Cir. 2006); *Sanchez v. Johnson*, 416 F.3d 1051, 1059-60 (9th Cir. 2005); *Long Term Care Pharm. Alliance v. Ferguson*, 362 F.3d 50, 59 (1st Cir. 2004); *Contra Pediatric Specialty Care, Inc. v. Ark. Dep't of Human Servs.*, 443 F.3d 1005, 1015-16 (8th Cir. 2006), *vacated on other grounds*, 551 U.S. 1142 (2007).

22 *Equal Access for El Paso, Inc.*, 509 F.3d at 704.

23 *Id.*

24 *Id.*

25 *See, e.g., Cal. Pharmacists Ass'n v. Maxwell-Jolly* (9th Cir. 2010) 596 F.3d 1098, *vacated on other grounds sub. nom. Douglas v. Indep. Living Ctr. of S. Cal., Inc.*, 132 S. Ct. 1204 (2012).

26 *See Osborn v. Bank of the United States*, 22 U.S. 738 (1824).

27 *Id.* at 838-39.

28 *Davis v. Gray*, 83 U.S. 203, 220 (1872).

29 U.S. Const. art. VI, cl. 2. The Supremacy Clause establishes that federal law is supreme so that incompatible state law is preempted and invalid.

30 209 U.S. 123 (1908).

31 *Id.*

32 *Id.* at 132.

33 *Id.* at 159-160.

34 *Id.* at 148.

35 *See, e.g., Planned Parenthood of Houston & Se. Tex. v. Sanchez*, 403 F.3d 324, 332-334 (5th Cir. 2005); *Crawford-El v. Britton*, 93 F.3d 813, 831-832 (D.C. Cir. 1996) (en banc) (Silberman, J., concurring), *rev'd on other grounds*, 523 U.S. 574 (1998); Richard H. Fallon, Jr., Daniel J. Meltzer & David L. Shapiro, *Hart & Wechsler's The Federal Courts & The Federal System* 903 (5th ed. 2003); 13D Charles A. Wright, Arthur R. Miller & Edward H. Cooper, *Federal Practice and Procedure* § 3566 (3d ed. 2008).

36 561 U.S. 477 (2010).

37 *Id.* at 491, n. 2.

38 *Id.*

39 *Id.*

40 *Green v. Mansour*, 474 U.S. 64, 68 (1985); *see also Armstrong v. Exceptional Child Center, Inc.*, 135 S.Ct. 1378, 1391 (2015) (Sotomayor, J., dissenting).

41 132 S. Ct. 1204 (2012).

42 *Indep. Living Ctr. of S. Cal., Inc. v. Maxwell-Jolly*, 572 F.3d 644 (9th Cir. 2009), *vacated and remanded by Douglas v. Indep. Living Ctr. of S. California, Inc.*, 132 S. Ct. 1204 (2012).

43 *Id.* at 1207.

44 *Id.* at 1211.

45 *Id.* When a state seeks to change how it administers its Medicaid program, as set forth in the agreement between the state and federal government (i.e., the "state plan"), it submits state plan amendments ("SPAs") to CMS for review and approval.

46 *See, e.g., Cal. Pharmacists Ass'n v. Maxwell-Jolly* (9th Cir. 2010) 596 F.3d 1098, *vacated on other grounds sub. nom. Douglas v. Indep. Living Ctr. of S. Cal., Inc.*, 132 S. Ct. 1204 (2012) (subsequent APA challenge to later enacted Medi-Cal rate reductions).

47 *Id.* at 1210.

48 *Id.*

49 *Exceptional Child Center, Inc. v. Armstrong*, 567 F. App'x 496 (9th Cir. 2014).

50 *Armstrong v. Exceptional Child Center, Inc.*, 135 S. Ct. 1378 (2015).

51 *Exceptional Child Center, Inc.*, 567 F. App'x at 497–98.

52 The Court did express "serious doubt" that the state's "inaction" in adopting higher rates could be preempted under the Supremacy Clause, but deemed any potential argument on this issue by the state to have been waived. 567 F. App'x at 498 n.2.

53 *Orthopaedic Hospital v. Belshe*, 103 F.3d 1491 (9th Cir. 1997).

54 The Ninth Circuit panel did not mention the Ninth Circuit's more recent decision in *Managed Pharmacy Care v. Sebelius*, 716 F.3d 1235 (May 24, 2013), where the Court, in the context of affirming the Secretary's approval of SPAs that included rate reductions, upheld the Secretary's interpretation that the Section 30(A) payment factors do not impose any particular methodology for considering provider costs.

55 The Supremacy Clause states: "This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2.

56 135 S. Ct. at 1383.

57 *Id.*

58 *Id.* at 1383-1384.

59 *Id.*

60 *Id.*

61 *Id.* at 1385.

62 *Id.* The authors of this article note, however, that the federal government's administrative enforcement tool — a revocation of funding — is extreme and would devastate rather than benefit the individuals whom Medicaid was designed to protect. In fact, the federal government has never cut funding to a state for violating the equal-access mandate.

63 135 S. Ct. at 1385.

64 *Id.*

65 *Id.* at 1386.

66 *Id.*

67 *Id.* at 1387.

68 *Id.*

69 *Id.*

70 *Id.*

71 *Id.* at 1388.

72 *Id.* (Breyer, J., concurring).

73 *Id.* (Breyer, J., concurring).

74 *Id.* (Breyer, J., concurring).

75 *Id.*at 1389 (Breyer, J., concurring).

76 *Id.* (Breyer, J., concurring).

77 *Id.* at 1390 (Breyer, J., concurring).

78 *Id.* (Breyer, J., concurring).

79 *Id.* (Sotomayor, J., dissenting).

80 *Id.* (Sotomayor, J., dissenting).

81 *Id.* at 1391 (Sotomayor, J., dissenting). Justice Sotomayor provided the following examples: "*Foster v. Love*, 522 U.S. 67, 118 S.Ct. 464, 139 L.Ed.2d 369 (1997) (state election law that permitted the winner of a state primary to be deemed the winner of election to Congress held preempted by federal statute setting date of congressional elections); *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 103 S.Ct. 2890, 77 L.Ed.2d 490 (1983) (state law preempted in part by the federal Employee Retirement Income Security Act of 1974); *Railroad Transfer Service, Inc. v. Chicago*, 386 U.S. 351, 87 S.Ct. 1095, 18 L.Ed.2d 143 (1967) (city ordinance imposing licensing requirements on motor carrier transporting railroad passengers held preempted by federal Interstate Commerce Act); *Campbell v. Hussey*, 368 U.S. 297, 82 S.Ct. 327, 7 L.Ed.2d 299 (1961) (state law requiring labeling of certain strains of tobacco held preempted by the federal Tobacco Inspection Act); *Railway Co. v. McShane*, 22 Wall. 444, 22 L.Ed. 747 (1875) (state taxation of land possessed by railroad company held invalid under federal Act of July 2, 1864)."

82 *Id.* at 1392 (Sotomayor, J., dissenting).

83 *Id.* at 1393 (Sotomayor, J., dissenting).

84 *Id.* (Sotomayor, J., dissenting).

85 *Id.* at 1394 (Sotomayor, J., dissenting).

86 *Id.* at 1395 (Sotomayor, J., dissenting).

87 *Id.* (Sotomayor, J., dissenting). As of the submission of this article for publication, the authors are unaware of any prologue to the case, as the authors do not believe the parties challenged the Idaho agency action under the APA.

88 Br. of *Amici Curiae*, Former HHS Officials at 4, *Douglas*, 2011 WL 3706105, at *4, *27 (filed Aug. 5, 2011); *see* Donenberg, Note, *Medicaid and Beneficiary Enforcement: Maintaining State Compliance with Federal Availability Requirements*, 117 Yale L.J. 1498, 1501–02 (2008).

89 *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 52 (1981) (White J., dissenting).

90 Donenberg, at 1502 (citation omitted).

91 *Florida Pediatric Soc., et al. v. Dudek*, No. 05-23036, (S.D. Fl. May 1, 2015). The court found that the "reasonable promptness" provision of § 1396a(a)(8), § 1396a(a)(10)'s requirement that medical assistance must be made available to all individuals who meet the eligibility standards (in this case, requiring that children receive medical and dental services known as Early Periodic Screening Diagnosis and Treatment ("EPSDT") services), and the

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requirement under § 1396a(a)(43) that states inform eligible individuals about available medical services ("effective outreach") all may be enforced through Section 1983 claims.

92 *But see Developmental Servs. Network v. Douglas*, 666 F.3d 540 (9th Cir. 2011) (holding that providers lacked ability to challenge failure by state to obtain federal approval under Section 1983, but explicitly limiting the challenge under Section 1983 and not the Supremacy Clause).

93 *See, e.g.*, Cal. Welf. & Inst. Code § 14079 (California statute requiring that the director of the Department of Health Care Services annually review Medi-Cal (California Medicaid) reimbursement rates for physician and dental services and requiring the periodic revision of those rates).

94 *See, e.g., California Hosp. Ass'n v. Maxwell-Jolly*, 188 Cal. App. 4th 559 (2010), *as modified on denial of reh'g* (Sept. 16, 2010) (writ of mandate action invalidating rate reduction for failure to comply with 42 U.S.C. § 1396a(a)(13)(A)'s notice requirements).

95 *See Douglas*, 132 S.Ct. at 1210.

96 *See, e.g., Managed Pharmacy Care v. Sebelius*, 716 F.3d 1235, 1245-50 (9th Cir. 2013).

97 Medicaid Program; Methods for Assuring Access to Covered Medicaid Services; Final Rule, 80 Fed. Reg. 67,576, 67,579.

98 *See* Medicaid and CHIP Managed Care Proposed Rule, 80 Fed. Reg. 31,098, 31,099 (June 1, 2015).

99 *See* Medicaid and CHIP Managed Care Proposed Rule, 80 Fed. Reg. at 31,144.

100 Medicaid Program; Request for Information (RFI) – Data Metrics and Alternative Processes for Access to Care in the Medicaid Program, 80 Fed. Reg. 67,377 (Nov. 2, 2015).

101 *Id.* at 67,378.

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THE MEDICINE SHOPPE V. LORETTA LYNCH, ET AL.: PHARMACISTS AND PRESCRIBING PHYSICIANS ARE EQUALLY LIABLE

Jeffrey C. Grass, JD, MS, ACLM
Jeffrey C. Grass & Associates
Plano, TX

On November 3, 2011, the Drug Enforcement Administration ("DEA") conducted an inspection of The Medicine Shoppe, a small family-owned pharmacy in San Antonio, Texas. DEA Diversion Investigators ("DIs") seized prescriptions filled by patients of a local physician who was under investigation for possible drug diversion. On October 7, 2013, the DEA Deputy Administrator issued an Order to Show Cause ("OTSC") to revoke The Medicine Shoppe's controlled substances Certificate of Registration ("COR") on the grounds that the pharmacy had filled prescriptions written by the target physician that were not for a "legitimate medical purpose."[1] The DEA alleged that The Medicine Shoppe's pharmacists failed to exercise their "corresponding responsibility," along with the physician, "to assure that its prescription for controlled substances was issued for a legitimate medical purpose" and "in the practitioner's usual course of professional practice" under DEA regulation.

The Medicine Shoppe responded that the pharmacists had known the patients and the prescribing physician for many years and had contacted the prescribing physician's office to verify the prescriptions before filling them.[2] The Medicine Shoppe argued that therefore it had complied with the requirements of their pharmacists' professional licenses and absent clear evidence of diversion, the pharmacists were obliged to fill the prescriptions.[3]

On October 2nd, 2014 the DEA revoked The Medicine Shoppe's COR.[4] The Medicine Shoppe then filed a Petition for Review with the United States Court of Appeals for the District of Columbia Circuit, which has original jurisdiction for appeals of DEA Orders under the Administrative Procedure Act ("APA").[5] The Medicine Shoppe appealed on the grounds that imposing a "corresponding responsibility" on pharmacists to ensure that controlled substances are prescribed for a "legitimate medical purpose'" requires them to make medical judgments beyond their education and training.[6] Moreover, should the DEA disagree with a physician's medical judgment and the medical necessity of a prescribed medication, pharmacists who now share a "corresponding responsibility," along with the physician, "to assure that its prescription for controlled substances was issued for a legitimate medical purpose" will be subject to the same civil and criminal liability for the physician, despite authenticating the order with the prescribing doctor, as required by state law.

Accordingly, Petitioners challenged the DEA's interpretation of "legitimate medical purpose" under the Controlled Substances Act ("CSA") and the "corresponding responsibility" standard under DEA Regulation 21 C.F.R. § 1306.04(a) (2014) on the grounds that these standards exceed the United States Attorney General's and the DEA's statutory authority under the CSA.[7]

On December 16, 2015, the Court denied The Medicine Shoppe's petition for review without comment, thereby leaving open the question of whether or not the United States Attorney General may expand the professional duty of pharmacists to require they either endorse or overrule the medical judgment of the prescribing physician.

The Backdrop of Expanding DEA Enforcement

The DEA has declared prescription drug abuse to be the Nation's fastest-growing drug problem.[8] It is of particular concern because legally obtained substances can lead to addiction or death.[9] One source of this problem is medical offices acting as "pill mills" and brick and mortar pharmacies working together promoting the illegal sale of pharmaceuticals.[10] In response to this epidemic, the DEA has stepped up its enforcement efforts against pharmacies suspected of diverting pharmaceutical medicines.[11] In doing so, the DEA has broadened the legal standard delineating licit from illicit dispensing of controlled substances.[12]

Controlled Substance Registration

The CSA and its implementing regulations "establish federal requirements regarding both illicit and licit controlled substances."[13] A "controlled substance" is defined as "a drug or other substance, or immediate precursor, included in Schedule I, II, III, IV, or V."[14] Under the framework of the CSA, enacted in 1970, "all controlled substance transactions take place within a 'closed system' of distribution established by Congress."[15] Accordingly, the DEA "requires all businesses that import, export, manufacture, or dispense controlled substances; all health care practitioners entitled to give out, administer, or prescribe controlled pharmaceuticals; and all pharmacies authorized to fill prescriptions, to register with the DEA."[16] The DEA has the unique dual responsibility to not only 1) ensure the supply of

pharmaceutical controlled substances for legitimate purposes, but also 2) prevent the diversion of these substances to illicit users/abusers.[17] The DEA administers this provision of the CSA by issuing a COR that authorizes a central individual or entity(s) ("Registrants") to dispense controlled substances in Schedules II thru V of the CSA.[18] According to the most recent tally by the Department of Health and Human Services Office of Inspector General ("OIG"), in March 2014 the DEA had 1.5 million active retail and wholesale Registrants.[19]

The DEA actively monitors these Registrants through a system of scheduling, quotas, recordkeeping, reporting, and security requirements.[20] The DEA also uses criminal and regulatory tools to identify and determine who is most likely involved in the illicit distribution of controlled substances.[21] The DEA initiates criminal investigations of those suspected of criminal violations of the CSA. Criminal prosecutions are coordinated with an Assistant United States Attorney or state District Attorney. Criminal cases vary widely in resource requirements and complexity.[22]

Administrative Inspection Warrants

Compliance inspections of pharmacies are carried out by the DEA Office of Diversion Control to ensure that the pharmacies have sufficient measures in place to prevent the diversion of controlled substances.[23] Noncompliance is determined primarily by investigating complaints about the dispensing practices of pharmacies.[24] The DEA's compliance review system includes web sites that monitor the prescribing and dispensing of controlled substances by physicians and pharmacies.[25] For example, the DEA uses the Automated Reports and Consolidated Order System ("ARCOS") to identify high volume purchasers of narcotic controlled substances.[26] Signs of suspicious circumstances are termed "red flags."[27] Red flags can constitute evidence of diversion from "legal and medically necessary uses towards uses that are illegal and typically not medically authorized or necessary."[28] If red flags are detected but left unresolved, the DEA will issue an Administrative Inspection Warrant ("AIW"). An AIW is an administrative search warrant that allows DEA DIs access to either a medical practice or pharmacy for the purpose of conducting compliance audits.[29]

Pharmacists' Duty to Identify and Resolve Red Flags

Individual pharmacists are now required to do more than just "verify the validity and authenticity of a prescription," as has historically been the case under state and federal law as well as DEA decisional history.[30] Pharmacists must also "resolve all red flags" before filling the prescription.[31]

Under this new regime, A pharmacist who "knowingly fills an order that is not intended for a legitimate medical purpose, as well as the physician issuing it, will be subject to the penalties provided for violations of the provisions of law relating to controlled substances under the CSA."[32] "Knowingly" includes circumstances that are known or should have been known to the pharmacist who may not "close [his or her] eyes and thereby avoid positive knowledge of the real purpose of the prescription, upon verifying that a physician issued it."[33] Keeping oneself unaware of facts that would render him or her liable in order to avoid civil or criminal liability is termed "willful blindness," "ignorance of the law," or "contrived ignorance" and is not a defense under the law.[34] Committing multiple violations of a pharmacist's "corresponding responsibility" can mean administrative or criminal prosecution resulting in the revocation of a pharmacy's COR, loss of the pharmacist's professional license, and possibly criminal prosecution under state or federal controlled substances statutes.[35]

Revoking Certificates of Registration and Orders to Show Cause

If the Registrant is believed to be non-compliant, the DEA may initiate an OTSC hearing as to why the Registrant's COR should not be revoked, suspended, or application for one denied.[36] This authority is derived from an amendment to the CSA in 1984, which "gives the United States Attorney General the power to revoke the federal registrations of physicians and pharmacists for the purpose of addressing the severe problem of diversion of drugs of legitimate origin into the illicit market."[37] If the DEA deems the violation to be egregious enough to pose an "imminent threat to public health or safety," the DEA may issue an immediate suspension order that summarily revokes the Registrant's authorization to prescribe or dispense controlled substances.[38] OTSC hearings and immediate suspension orders are collectively known as "Registrant Actions."[39] Since the DEA grants a COR to a pharmacy and not the pharmacist, this legal action refers to the practices of the store, although the actual parties being scrutinized are the pharmacy owners and the registered pharmacists operating it.[40]

Once the DEA Administrator issues an OTSC, the Registrant may either allow the DEA Administrator to issue a Final Decision and Order modifying or revoking the pharmacy's COR or request an OTSC due process hearing.[41] If the Registrant wants a hearing, a DEA Administrative Law Judge ("ALJ") hears evidence presented by DEA Counsel and the Registrant. The ALJ will make findings as to whether or not a preponderance of the evidence submitted shows the Registrant's continued registration is "inconsistent with the public interest."[42] The ALJ will then issue his or her Findings of Fact, Conclusions of Law and a Recommended Decision to the DEA Administrator. The DEA

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Administrator may agree or disagree with the recommendation of the ALJ and will render his or her final Decision and Order adopting, modifying or rejecting the ALJ's Findings of Fact, Conclusions of Law and a Recommended Decision.[43]

Pharmacists "Corresponding Responsibility"

The DEA Administrator's decision to allow a pharmacy to continue dispensing controlled substances depends, in part, on whether it has acted responsibly in filling prescriptions. DEA regulations require pharmacists have a "corresponding responsibility," along with the physician, "to assure that a prescription for a controlled substance "was issued for a legitimate medical purpose" and "in the practitioner's [physician's] usual course of professional practice."[44] An order purporting to be a prescription issued not in the usual course of professional treatment or a legitimate medical purpose is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.[45] In other words, the DEA make pharmacists as equally responsible as the prescribing doctor that medications the pharmacy dispenses are necessary for treating a patient's medical condition.[46]

Controlled Substances Must Be for a "Legitimate Medical Purpose"

Although the "legitimate medical purpose" standard has existed for more that 90 years, the phrase is not defined in the CSA, and this omission invites conjecture about its meaning.[47] For the most part, "legitimate medical purpose" has been construed by the federal courts and DEA decisional history to require that dispensing controlled substances be done "in accordance with a standard of medical practice recognized and accepted in the United States."[48] However, the United States Attorney General and state legislatures have repeatedly been at odds when the DEA has interpreted its statutory authority under the CSA in a way that enables it to control healthcare policy.[49] For example, at issue in The Medicine Shoppe case was whether the DEA may interpret this phrase to decide medical standards of care and require pharmacists to judge whether prescribed medications are necessary to treat a patient's medical condition.[50]

Federal Pre-emption v. State Police Powers

Since medical standards of care are traditionally determined by the states, a tension has developed between federal and state enforcement in discerning whether a practice is for a "legitimate medical purpose" or "illegitimate nonmedical purpose."[51] More particularly at issue in *The Medicine Shoppe* case is whether the United States Attorney General may expand the professional duty of pharmacists to require that they either endorse or overrule the medical judgment of the prescribing physician. Under Texas state law, and the law of most other states, pharmacists have the duty to "exercise sound professional judgment with respect to the accuracy and authenticity of any prescription drug order dispensed. If the pharmacist questions the accuracy or authenticity of a prescription drug order, the pharmacist shall verify the order with the practitioner before dispensing."[52] "A prescription drug order may not be dispensed or delivered if the pharmacist has reason to suspect that the prescription drug order may have been authorized in the absence of a valid patient-practitioner relationship, or otherwise in violation of the practitioner's standard of practice[.]"[53] Historically, the DEA's interpretation of pharmacists' duty under the CSA is to require they verify the validity and authenticity of the prescription with the prescriber and to deny the order if it appears suspicious.[54]

However, the DEA contends that it has the authority to expand the professional duty of pharmacists to require they either endorse or overrule the medical judgment of the prescribing physician even if contrary to state law. The United State's Attorney General interprets the CSA's preemption provision, 21 U.S.C. 903, as clearly demonstrating that "Congress expressly intended that there would be a dual system of Federal-State regulation of controlled substances," which reflects that this field of regulation was to be shared by the federal and state governments.[55]

This provision reiterates what is inherent in the Supremacy Clause of the United States Constitution – that no state may enact a law relating to controlled substances that present a "positive conflict" with the CSA. The DEA cites the preceding language of the CSA as its authority to make a determination, independent of state regulators, whether the Registrant's continued authority to handle controlled substances would follow the public interest.[56] Yet, expanding this interpretation in a way that grants the United States Department of Justice the power to determine medical necessity has consistently put the federal government at odds with the states' ability to regulate the use and dispensing of controlled substances.

Conflicting Applications of the "Legitimate Medical Purpose" Standard

Chronic Pain Management

In *United States v. Moore*, the United States Supreme Court upheld the conviction of a physician alleged to have "knowingly or intentionally, dispensed or distributed [methadone] by prescription, and who did so other than in good faith in the usual course of a professional practice and in accordance with a standard of medical practice generally recognized and accepted in the United States."[57]

However, the Court clarified that the CSA extends only to issues related to a practitioner's federal registration and "extends no further."[58] In so doing, the *Moore* Court limited the DEA's authority to regulate transactions within "the legitimate distribution chain."[59] Therefore, the holding in *Moore* did not interpret the CSA to "authorize the DEA to set standards of care, but rather reserves those questions for the States."[60] Nor did the Court extend the ruling to impose an independent duty or "corresponding responsibility" for the medical necessity of the prescribed medications on pharmacists.[61] The Court observed that these were medical standards of care that have traditionally been relegated to the states and applied to the prescribing practitioner.[62] Therefore, scrutiny of pharmacy practice by the DEA had historically been limited to issues concerning the manner in which controlled substances are stored and distributed.[63]

Medical Marijuana

However, the authority of the United States Attorney General to set healthcare policy under the doctrine of preemption was embraced by the United States Supreme Court in *Gonzales v. Raich* (previously *Ashcroft v. Raich*). In *Raich*, the Court held that the United States Congress may criminalize the production and use of medical marijuana even where the states approve its use as medically necessary and for a "legitimate medical purpose."[64] Here, the Court acknowledged Congressional intent to criminalize the possession and use of marijuana for all purposes as a Schedule I controlled substance.[65] Consequently, federal law and the United States Attorney General's enforcement of the CSA preempt state law under the Commerce Clause of the United States Constitution when Congress has manifested its clear intention to do so.[66]

Death with Dignity

Yet a year later, the Court in *Gonzales v. Oregon* expressly limited the DEA's role in evaluating the medical usefulness of a prescription drug. The *Gonzales* Court held that "the states, not the DEA, have the authority to determine what orders have been issued for a 'legitimate medical purpose.'"[67] The Court said that the authority delegated by the United States Attorney General permits the DEA to deny, suspend, or revoke a registration that would be "inconsistent with the public interest."[68] In determining consistency with the public interest, the Attorney General must consider five factors, including the state's recommendation, compliance with state, federal, and local law regarding controlled substances, and public health and safety.[69] The CSA explicitly contemplates a role for the states in regulating controlled substances. However, the *Gonzales* Court found substantial limitations in the implementation of the CSA by the DEA in this regard.[70] Justice Kennedy, writing for the Court, stated:

> The CSA and this Court's case law amply support the conclusion that Congress regulates medical practice insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood. Beyond this, the Act manifests no intent to regulate the practice of medicine generally, which is understandable given federalism's structure and limitations. The CSA's structure and operation presume and rely upon a functioning medical profession regulated under the States' police powers. The Federal Government can set uniform standards for regulating health and safety. In connection with the CSA, however, the only provision in which Congress set general, uniform medical practice standards, 42 U.S.C. § 2990bb2a, strengthens the understanding of the CSA as a statute combating recreational drug abuse and also indicates that when Congress wants to regulate medical practice in the given scheme, it does so by explicit statutory language.[71]

Consequently, the *Gonzales* Court adhered to a policy of "continuing to give deference to the opinions of the state licensing authorities."[72] By ruling for the state of Oregon, the Supreme Court is requiring that states, through their legislatures, professional licensing boards, and citizen initiatives, will continue to decide what uses of medications are for a legitimate medical purpose.[73]

Furthermore, the *Gonzales* Court and its progeny reveal a reluctance to grant the DEA the absolute authority to impose upon pharmacists civil or criminal liability arising from a "corresponding responsibility with physicians that controlled substances are intended for a legitimate medical purpose" unless there is direct evidence that the pharmacist had actual knowledge that the prescribing physician is diverting drugs. That means that the pharmacist knew that the doctor has "knowingly or intentionally, dispensed or distributed by prescription, other than in good faith in the usual course of professional practice and in accordance

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with a standard of medical practice recognized and accepted in the United States."[74] Therefore, "[a]cts of prescribing or dispensing of controlled substances that are done within the course of the registrant's professional practice are, for purposes of the Controlled Substances Act, lawful. It matters not that such acts might constitute terrible medicine or malpractice. They may reflect the grossest form of medical misconduct or negligence. They are nevertheless legal."[75] Moreover, "[i]n making a medical judgment concerning the right treatment for an individual patient, physicians require a certain latitude of available options."[76] Hence, "[w]hat constitutes Bona fide medical practice must be determined upon consideration of the evidence and attending circumstances."[77] However, under the guise of treatment, a physician cannot prescribe, and a pharmacy cannot sell drugs to a dealer nor distribute drugs intended to cater to cravings of an addict.[78] Congress did not intend for doctors to become drug pushers. This general principle does not diminish the difficulty in the application of the legal standards set forth for the proper prescribing and dispensing of controlled substances.[79]

Lethal Injection

Because sodium thiopental is a Schedule III drug, the CSA requires a qualified medical practitioner to write a prescription for the drug before it may be dispensed.[80] As lethal injection has become the near exclusive method of execution in this country, challenges to capital punishment will migrate from federal U.S. Constitutional amendment VIII challenges involving cruel and unusual punishment to whether the drugs used have been dispensed and administered for a "legitimate medical purpose."[81] Based on this position, the DEA can no longer consistently hold that it should not regulate the drugs used in lethal injections.[82]

Clear Examples of Illicit Purposes

Decisions in the Fifth Circuit and Sixth Circuit have provided some, but not much guidance to pharmacists as to how they define "legitimate medical purpose," but mostly these decisions tell stakeholders what is not considered a legitimate medical purpose. In *United States v. Rosen*, the Court of Appeals observed that "[a] majority of cases [in which physicians were alleged to have dispensed controlled substances without a legitimate medical purpose] have dealt with facts which were so blatant that a statement of clear-cut criteria in a form useful in other cases would have been superfluous to the decision."[83] The *Rosen* Court did, however, "glean from reported cases certain recurring concomitance of condemned behavior to include conclusive evidence of wrongdoing such as providing multiple prescriptions to individuals in fictitious names to avoid detection; trading drugs for sexual favors or money; or, physicians who sell prescriptions to drug dealers or abusers; and evidence of illicit sales."[84]

In *United States v. August*, the Court of Appeals for the Sixth Circuit stated that "there are no specific guidelines concerning what is required to support a conclusion that an accused acted outside the usual course of professional practice…. [Rather, the courts] "must engage in a case-by-case analysis of evidence to determine whether a reasonable inference of guilt may be drawn from specific facts."[85] The *August* Court's holding essentially declared that the judiciary was no more qualified than the DEA to say what a "legitimate medical purpose" is, but could say in particularly blatant cases what it is not by including a few condemned behaviors that are so flagrant as to warrant concern. For example, (1) an inordinately large quantity of controlled substances was prescribed;[86] (2) large numbers of prescriptions were issued;[87] (3) no physical examination was given;[88] (4) the physician warned the patient to fill prescriptions at different drug stores;[89] (5) the physician issued prescriptions for a patient known to be delivering the drugs to others;[90] (6) the physician prescribed controlled drugs at intervals inconsistent with legitimate medical treatment;[91] (7) the physician involved used street slang rather than medical terminology for the drugs prescribed;[92] (8) there was no logical relationship between the drugs prescribed and treatment of the condition allegedly existing; and (9) the physician wrote more than one prescription on occasions to spread them out.[93]

The Medicine Shoppe v. Loretta Lynch, et. al.

Factual Background

As noted above, The Medicine Shoppe Pharmacy is a small, family-owned, franchised pharmacy located in San Antonio, Texas. In October 2011, the DEA executed an AIW in connection with its investigation of a local physician. Neither the Pharmacist-In-Charge ("PIC") nor the pharmacy itself had ever been the subject of a complaint.[94]

On October 7, 2013, two years after the AIW was executed, the DEA Deputy Administrator issued an OTSC to revoke The Medicine Shoppe's COR. The grounds for the OTSC were that the pharmacy, two years prior, filled prescriptions written by the physician under investigation and that these prescriptions should not have been filled because they presented unresolved red flags. According to the DEA, the prescriptions presented red flags because, among other things, they were written for the "holy trinity drug cocktail" of hydrocodone, Xanax and Soma (a muscle relaxant),

and were suspicious for that reason.[95] The Medicine Shoppe responded that its pharmacists had known the patients and the prescribing physician for many years.[96] Moreover, the PIC explained that before filling the prescriptions, the pharmacist contacted the prescribing physician's office to verify the authenticity of the order, the identity of the patient, the physician's contact information and DEA number and the drug dosages. The doctor confirmed this information.[97] Therefore, The Medicine Shoppe's pharmacists maintained that they had complied with their professional duty within the parameters of their education, training and the scope of their professional licenses.[98] Moreover, the pharmacists insisted that absent clear evidence of diversion, the pharmacy was obligated to fill the order.[99]

On January 7, 2014, an OTSC hearing was held in San Antonio, Texas, before the DEA's ALJ. Under her review of the evidence presented by the parties, the ALJ recommended the revocation of The Medicine Shoppe's COR, and "to deny any pending applications for renewal or modification of such registration."[100] On October 2, 2014 DEA Deputy Administrator Thomas Harrigan issued his Final Decision and Order, revoking The Medicine Shoppe's DEA COR on the basis that its continued registration would be "inconsistent with the public interest."[101] The Deputy Administrator's Order was premised upon his finding that The Medicine Shoppe's pharmacists had failed to exercise their "corresponding responsibility," along with the physician, "to assure that its prescription for controlled substances was issued for a legitimate medical purpose" and "in the practitioner's usual course of professional practice."[102]

The Medicine Shoppe then filed a Petition for Review with the United States Court of Appeals for the District of Columbia Circuit challenging this ruling on three principal grounds: 1) whether the manner in which the DEA currently imposes on pharmacies a "corresponding responsibility with physicians" exceeds its authority under the CSA; 2) whether the DEA requires pharmacists to act beyond the scope of their state-issued professional licenses by requiring them to make judgments about the medical necessity of the controlled substances being prescribed by practitioners; and 3) whether the "legitimate medical purpose" standard is inconsistently defined and applied by the DEA, thus resulting in arbitrary enforcement actions.[103]

On December 16, 2015, the Appeals Court denied The Medicine Shoppe's Petition for Review without comment or memorandum, resulting in the current state of the law.

The DEA Exceeds Its Authority Under the CSA

The Medicine Shoppe unsuccessfully argued that the DEA exceeds its statutory authority under the CSA by interpreting the "legitimate medical purpose" provision of the CSA to grant the United States Attorney General the power to (1) impose medical standards of care for physicians; and (2) impose a "corresponding responsibility" on pharmacists as well as the prescribing doctors. This interpretation continues to grant the DEA the same broad authority allowed by the United States Supreme Court in *Moore* and *Raich* but rejected in *Gonzales*, which adhered to a policy of "continuing to give deference to the opinions of the state licensing authorities."[104]

The Medicine Shoope advocated that the states, through their legislatures, professional licensing boards, and citizen initiatives, should continue to decide what uses of medications are for a legitimate medical purpose.[105] Furthermore, The Medicine Shoppe attempted to persuade the Court of Appeals that it follow the *Gonzales* Court and its progeny's reluctance to grant the DEA the absolute authority to impose upon pharmacists civil or criminal liability arising from a "corresponding responsibility with physicians that controlled substances are intended for a legitimate medical purpose" unless there is direct evidence that the pharmacist had actual knowledge that the prescribing physician was diverting drugs.[106] That means that the pharmacist knew that the physician has "knowingly or intentionally, dispensed or distributed by prescription, other than in good faith in the usual course of a professional practice and in accordance with a standard of medical practice generally recognized and accepted in the United States."[107] The Court did not accept these arguments, arguably permitting the federal government to make medical judgments concerning medical necessity beyond setting standards for regulating health and safety combating drug abuse. This authority would presumably allow the Department of Justice to make determinations concerning medical necessaity in other areas of law where "medical necessity" is the benchmark for eligibility of benefits and also criminal prosecution.[108]

The DEA Requires Pharmacists to Act Beyond the Scope of Their State License

The Medicine Shoppe argued that the DEA regulation imposing a "corresponding responsibility" on pharmacists to ensure that controlled substances are prescribed for a "legitimate medical purpose" requires they act beyond the scope of their state-issued professional licenses and make judgments about the medical necessity of the controlled substances being prescribed by practitioners. This corresponding responsibility requires pharmacists and pharmacy owners to do more than just verify the authenticity of a prescription for controlled substances;[109] they must now make judgments about the medical necessity of the controlled substances being prescribed by practitioners.[110]

Although The Medicine Shoppe contended that this standard requires

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pharmacists take affirmative action beyond their education, training and professional license, the DEA maintained that its regulation requires no pharmacist to exercise, overrule, or second-guess a physician's medical judgment.[111] Rather, it requires a reasonable assessment, within the pharmacist's competence, of whether the prescribing practitioner has exercised medical judgment.[112] The DEA further explained that "a pharmacist must exercise professional judgment when filling a prescription issued by a physician" and may not reasonably claim that, when presented with a prescription that raised suspicion, state law required its pharmacists to "close [their] eyes and thereby avoid positive knowledge of the real purpose of the prescription" upon verifying that a physician issued it."[113] The Court of Appeals agreed with the DEA.[114]

The DEA's "Legitimate Medical Purpose" Standard is Vague and Arbitrary

The Medicine Shoppe also argued, unsuccessfully, that the "legitimate medical purpose" standard is vague and arbitrary because its is not grounded upon any particular medical standard of care establishing what constitutes proper prescribing, negligent prescribing and criminal drug diversion under the CSA and DEA regulations.[115] However, the DEA has refused to set such standards, stating its policy is that "the government can investigate merely on suspicion that the law is being violated, or even just because it wants assurance that it is not."[116] The DEA further asserted that "it would be incorrect to suggest that DEA must meet some arbitrary standard or threshold evidentiary requirement to commence an investigation of a possible violation of the [CSA]."[117]

As a result, some stakeholders fear that the Court of Appeals decsion clears the way for the DEA to insert itself into the sensitive equation of the physician-patient relationship, requiring federal law enforcement to make medical and scientific interpretations that should be made by state regulatory authorities.[118] This fear has increased the risk of a chilling effect on prescribers and pharmacists to provide needed medicines.[119] This concern is especially true for the treatment of pain.[120]

Conclusion

Best Practices for Pharmacies

The CSA, when introduced over 40 years ago, was a much-needed attempt to stem the abuse of licit and illicit drugs in American society. The numerous amendments to the CSA since then exemplify the difficulties in defining and controlling such a vast and complex problem. The challenges faced in determining the diversion of prescriptive controlled substances in such a way as not to negatively affect the practice of medicine and treatment of pain especially proves to be no less difficult a task. A fresh perspective on the matter is needed to provide better guidance. This change should be considered in light of the relatively long period that has passed since this subject was last addressed by the courts, the vast improvements in technology and our increased understanding of the effects drugs have on the human body. *The Medicine Shoppe*[121] provides some guidance to pharmacists and pharmacy owners in understanding their "corresponding responsibility to assure that [their] prescriptions for controlled substances are issued for a legitimate medical purpose" and "in the practitioner's usual course of professional practice."

Pharmacists need to remain vigilant in the war against drug abuse and pill mills and decline to fill prescriptions for controlled substance that are suspicious. Pharmacies and the pharmacists operating them are not immune from administrative, regulatory or criminal prosecution under the CSA solely because they have verified a prescription with the prescribing doctor. Rather, they are expected to dispense drugs for the bona fide treatment of a patient's disease. In doing so, they must exercise sound professional judgment when evaluating the legitimacy of a controlled substance prescription. Pharmacists must "resolve all red flags" before filling the prescription. The law does not require pharmacists to dispense every medication, especially if the order is suspicious. To the contrary, pharmacists who deliberately ignore red flags that give them a reason to believe the medication does not serve a legitimate medical purpose may be prosecuted, along with the issuing practitioner, as a drug trafficker. The price is steep; drug trafficking is a felony offense, which may result in the loss of one's COR, professional license or even criminal prosecution.[122]

Jeffrey C. Grass, JD, MS, FCLM, is former US Navy JAG. He was awarded Navy Commendations and Naval Achievement medals for meritorious service. He has represented physicians and pharmacists for more than 22 years. He maintains a national practice and has appeared before the U.S. Supreme Court, the U.S. Fifth Circuit Court of Appeals and the U.S. Court of Appeals for the DC Circuit.

Mr. Grass is a Fellow of the American College of Legal Medicine and a Member of the State Bar College of Texas. He also sits on the Advisory Board for The Champion Magazine, a monthly publication of the National Association of Criminal Defense Lawyers. Mr. Grass is a member of the American Bar Association's Committees on Criminal Justice and Healthcare. Jeffrey may be reached at (972) 422-9999, Fax: (972) 423-2646, or *Jeff@Grasslaw.com*.

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Endnotes

1 The DEA sought revocation despite the fact neither the Pharmacist-In-Charge ("PIC") nor the pharmacy itself had ever been the subject of a prior complaint or investigation under 21 U.S.C. § 812 (2012). *In the Matter of the Medicine Shopp*e Federal Register / Vol. 79, No. 191 / Thursday, October 2, 2014 / Notices 59504 to 59517.

2 *See The Medicine Shoppe v. Loretta Lynch, et al.* 14-223 (2014) Pet. Br. at 4. On January 7, 2014, an OTSC hearing was held in San Antonio, Texas, before the DEA's ALJ. Pursuant to her review of the evidence presented by the parties, the ALJ issued her *Recommended Findings of Fact, Conclusions of Law and Decision of the Administrative Law Judge* to the DEA Deputy Administrator, Thomas M. Harrigan. The ALJ recommended the revocation of The Medicine Shoppe's COR under 21 U.S.C. § 824(a), and "to deny any pending applications for renewal or modification of such registration under 21 U.S.C. § 823(f)." 79 Fed. Reg. 191 (Jan. 2, 2014) pgs. 59504-59517 – *In the Matter of the Medicine Shoppe; Decision and Orde*r (October 2, 2014).

3 *See The Medicine Shoppe v. Loretta Lynch, et al.* 14-223 (2014) Pet. Br. at 4.

4 Deputy Administrator Harrigan issued his final *Decision and Order*, Docket No. 14-01 revoking The Medicine Shoppe's DEA Certificate of Registration ("COR") BT8599891 under 21 U.S.C. §§ 823(f), 824(a), on the basis that its continued registration would be "inconsistent with the public interest," 21 U.S.C. § 59505.

5 5 U.S.C. § 551 (2012) *et seq.*

6 Pet. Br. At 15-17, *The Medicine Shoppe*: Decision and Order | Insurance News Net, http://insurancenewsnet.com/oarticle/2014/10/02/the-medicine-shoppe-decision-and-order (last accessed August 19, 2015).

7 *The Medicine Shoppe v. Loretta Lynch, et. al.* 14-1223 (D.C. Cir. 2014). Pet. Br. 11-16.

8 U.S. Department of Justice Drug Enforcement Administration FY 2014 Performance Budget Congressional Submission DEA-18.

9 Denisco, R. A. "A pharmacist who knowingly fills a prescription that is not intended for a legitimate medical purpose, as well as the physician issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances under the Federal Controlled Substances Act ("CSA")," Chandler, R. K., & Compton, W. M. (2008), Addressing the Intersecting Problems of Opioid Misuse and Chronic Pain Treatment. *Experimental and Clinical Psychopharmacology*, *16*(5), 417–428.

10 U.S. Department of Justice Drug Enforcement Administration FY 2016 Performance Budget Congressional Submission, DEA-21.

11 The DEA's Diversion Control Program ("DCP") is responsible for enforcing the CSA and its regulations pertaining to pharmaceutical controlled substances and listed chemicals.

12 "Drug Diversion in the Medicaid Program: State Strategies for Reducing Prescription Drug Diversion in Medicaid," Centers for Medicare & Medicaid Services (Baltimore, MD: January 2012), p. 1. "Drug diversion" is best defined as the diversion of licit drugs for illicit purposes.

13 21 U.S.C. § 801 *et seq.*

14 21 U.S.C. § 802(6).

15 "The DEA was established in 1973 to serve as the primary agency responsible for the enforcement of federal drug laws." Controlled Substances Act, DEA Diversion Control Program Pharmacist's Manual.

16 21 U.S.C. § 801 *et seq.* and 21 C.F.R. pt. 1300 (2014) *et seq.*

17 Controlled Substances Act, DEA Diversion Control Program Pharmacist's Manual.

18 *U.S. Department of Justice Drug Enforcement Administration FY 2015 Performance Budget Congressional Submission, DEA-79.* No prescriptions may be written for Schedule I substances, and they are not readily available for clinical use. Schedule I drugs are those that have a high potential for abuse. The drug or other substance has no currently accepted medical treatment use in the United States. There is also a lack of accepted safety for use of the drug or substance under medical supervision. The Substances listed in DEA Schedule I include:

Heroin (diacetylmorphine)

LSD (Lysergic acid diethylamide)

Marijuana (cannabis, THC)

Mescaline (Peyote)

MDMA (3,4-methylenedioxymethamphetamine or "ecstasy")

GHB (gamma-hydroxybutyric acid)

Psilocybin

Methaqualone (Quaalude)

Khat (Cathinone)

Bath Salts (3,4-methylenedioxypyrovalerone or MDPV)

NOTE: Tetrahydrocannabinol (THC, marijuana) is still considered a Schedule I drug by the DEA, even though some states have legalized marijuana for personal, recreational, or medical use.

19 The Drug Enforcement Administration's Adjudication of Registrant Actions, Evaluation, and Inspections *Report* I-2014-003. p. 2.

20 U.S. Department of Justice Drug Enforcement Administration FY 2016 Performance Budget Congressional Submission DEA-81.

21 *Ibid.* at DEA – 93.

22 *Ibid.*

23 *Ibid.*

24 *Ibid.*

25 According to the National Alliance for Mode l State Drug Laws (NAMSDL), a Prescription Drug Monitoring Program (PDMP) is a statewide electronic database which collects designated data on substances dispensed in the state. The PDMP is housed by a specified statewide regulatory, administrative or law enforcement agency. The housing agency distributes data from the database to individuals who are authorized under state law to receive the information for purposes of their profession.

26 *Ibid.* at DEA-12.

27 *See United States v. Ilayayev*, 800 F. Supp. 2d 417, 2011 U.S. Dist. LEXIS 87012 (E.D.N.Y., 2011) (holding that red flags are sufficient for the DEA to issue an OTSC).

28 "Drug Diversion in the Medicaid Program: State Strategies for Reducing Prescription Drug Diversion in Medicaid," Centers for Medicare & Medicaid Services (Baltimore, MD: January 2012), p. 1.

29 21 C.F.R. § 1316.07, Requirement for administrative inspection warrant; exceptions.

30 *See Holiday CVS, L.L.C., d/b/a CVS Pharmacy Nos. 219 and 5195*, 77 Fed. Reg. at 62,340-41 (interpreting 21 C.F.R. § 1306.04(a) limiting a pharmacists' duty to determine the legitimacy of a prescription).

31 *A Pharmacist's Obligation: Corresponding Responsibility and Red Flags of Diversion* By Larry Cote on August 11, 2013, posted in *DEA Compliance*.

32 21 C.F.R. § 1306.04(a).

33 *The Medicine Shoppe*, 14-1223 Resp. Br. 10 (citing *Ralph J. Bertolino, d/b/a Ralph J. Bertolino Pharmacy*, 55 Fed. Reg. 4729, 4730 (1990) (interpreting pharmacists' duty under 21 U.S.C. §§ 823, 824).

34 Luban, David. Contrived Ignorance (1999), Vol. 87 Georgetown Law Journal, 957.

35 In other words, DEA regulations make pharmacists liable, with prescribing physicians, for both negligent and criminal acts. The CSA is found in Title 21 of United States Code (21 U.S.C.) 801-971 and the DEA regulations, Title 21, C.F.R Parts 1300 to End 21 U.S.C. § 812.

36 https://oig.justice.gov/reports/2014/e1403-summary.pdf.

37 S. Rep. No. 98-225 at 260, 261-62, 1984 U.S.C. C.A.N. at 343-344) (granting authority to the Attorney General to delegate regulatory authority to the DEA).

38 21 U.S.C. §§ 823 & 824, https://www.oig.justice.gov/reports/2014/e1403.pdf.

39 FY 2014 Annual Performance Report and FY 16 Annual Performance Report available *at* http://www.justice.gov/sites/default/files/doj/pages/attachments/2015/02/06/fy14.

40 ARTICLE: DRUG DIVERSION ADMINISTRATIVE REVOCATION AND APPLICATION HEARINGS FOR MEDICAL AND PHARMACY PRACTITIONERS: A PRIMER FOR NAVIGATING MURKY, DRUG-INFESTED WATERS, 78 Alb. L. Rev. 327 (2014).

41 DEA Regulation 21 C.F.R. § 1307.37(c) states: "OTSC shall call upon registrant to appear before the Administrator and contain a statement of the legal basis for such hearing and for the denial, revocation, or suspension of the registration and a summary of the matters of fact and law asserted."

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42 21 U.S.C. § 824.

43 SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT, *available at* http://leg.state.fl.us/data/session/2001/Senate/bills/analysis/pdf/2001s1042.

44 21 C.F.R. 1306.04(a).

45 *Ibid.*

46 *A Pharmacist's Obligation: Corresponding Responsibility and Red Flags of Diversion* by Larry Cote on August 11, 2013, posted in *DEA Compliance*.

47 Colin Miller, Death by Any Other Name: The Federal Government's Inconsistent Treatment of Drugs Used in Lethal Injections and Physician-Assisted Suicide, 17 J.L. & Health 217 (2002-2003).

48 *See United States v. Moore*, 423 U.S. 122, 139 (1975) (quoting jury instructions).

49 U.S. Const. amend. X. In United States constitutional law, police power is the capacity of the states to regulate behavior and enforce order within their territory for the betterment of the health, safety, morals, and general welfare of their inhabitants. Controversies over the exercise of police power arise when its exercise by the federal government conflicts with the rights of the states, or when its exercise by federal or state authorities conflicts with individual rights and freedoms. Willrich, Michael (2012). Pox. New York: Penguin. p. 302. ISBN 978-0-14-312078-0.

50 DISPENSING CONTROLLED SUBSTANCES FOR THE TREATMENT OF PAIN. FR Doc E6-14517 [Fed. Reg.: September 6, 2006 (Volume 71, Number 172)] [Notices] [Page 52715-52723].

51 *Ibid.*

52 Tex. Admin.Code (TAC) Title 22, Part 15 TSBP Rule § 291.29(a).

53 *Ibid.*at § 291.29(b)(2), Professional Responsibility of Pharmacists.

54 77 Fed. Reg. at 62,340-41.

55 21 U.S.C. 903 states: "No provision of this subchapter shall be construed as indicating an intent on the part of Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State."

56 21 C.F.R. 1306; DEA Policy Statement: Dispensing Controlled Substances for the Treatment of Pain; Notice [Docket No. DEA–286P] Fed. Reg. / Vol. 71, No. 172 / Wednesday, September 6, 2006 / Notices at 52716-52717. *Mark P. Koch, D.O.*, 79 Fed. Reg. 18,714, 18,719 (Apr. 3, 2014).

57 *United States v. Moore*, 423 U.S. 122 (1975), 423 U.S. at 138-39.

58 *Moore*, 423 U.S. at 141 (citing H.R.Rep. No. 91-1444, p. 3).

59 *Ibid.*

60 *Moore*, 423 U.S. at 423.

61 *Ibid.*

62 *Ibid.*

63 *Ibid.*

64 *Gonzales v. Raich* (*previously Ashcroft v. Raich*), 545 U.S. 1 (2005). California voters passed Proposition 215 in 1996, legalizing the medical use of marijuana. Defendant Angel Raich used homegrown medical marijuana, which was legal under California law but illegal under federal law. Angel Raich's physician had stated that, without marijuana, Angel's life is threatened by excruciating pain. Raich sued to enjoin enforcement of the CSA against him claiming that doing so would violate the Commerce Clause, the Due Process Clause of the U.S. Const. amend. V, the U.S. Const. amend. IX, the U.S. Const. amend. X, and the doctrine of medical necessity.

65 U.S. Const. amend. X.

66 *Supra* n. 18.

67 *Gonzales v. Oregon*, 546 U.S. 243 (2006), at 244.

68 21 U.S.C. § 824(a) (4), 822(a)(2).

69 21 U.S.C. §823(f).

70 21 U.S.C. §903.

71 *Id.* at 244.

72 *See Gregory v. Ashcroft,* 501 U.S. 452, 461, (1991) (holding that states' police powers grant them exclusive authority to set licensing standards).

73 In 1994, the state of Oregon enacted by ballot measure the Oregon Death with Dignity Act, the country's first law authorizing physician-assisted suicide. Alexander DeLuca, M.D. Addiction, Pain, & Public Health. Affirmation of States' Authority to Define "Legitimate Medical Purpose" Citing David B. Brushwood. J.D; American Journal of Health-Systems Pharmacy; 63(5); 2006, posted: 2006-03-18.

74 *Moore*, 423 at 138-39.

75 Stone S. The investigation and prosecution of professional practice cases under the Controlled Substances Act. Drug Enforcement (newsletter). 1983, page 21.

76 *See United States v. Collier*, 478 F.2d 268, 271-72 (5th Cir. 1973) (citing *Doe v. Bolton*, 410 U.S. 179, 93 S.Ct. 739, 747, 35 L.Ed.2d 201 (1973).

77 *Linder v. United States*, 68 U.S. (5) at 18, 45 S.Ct. (446) at 449, (69 L.Ed. 819 (1925)).

78 *August*, 984 F.2d at 713 (6th Cir. 1992).

79 *Ibid.*

80 21 C.F.R. § 1308.13(c)(1)(iii), 21 U.S.C. §§ 829(b), 841(a)(1).

81 In 2006, the Supreme Court ruled in *Hill v. McDonough,* 437 F. 3d 1084 that death row inmates in the United States could challenge the constitutionality of states' lethal injection procedures through a federal civil rights lawsuit. Since then, numerous death row inmates have brought such challenges in the lower courts, claiming that lethal injection as currently practiced violates the ban on "cruel and unusual punishment" found in the Eighth Amendment to the United States Constitution." Memorandum of Intended Decision (Morales)" *(PDF). Death Penalty Clinic, UC Berkeley School of Law. 2006-12-15.*

82 *Ibid.*

83 *United States v. Rosen*, 582 F.2d 1032, 1033 (5th Cir. 1978).

84 *Ibid.*

85 *United States v. August*, 984 F.2d 705, 713 (6th Cir. 1992).

86 *United States v. Behrman*, 258 U.S. 280, 42 S. Ct. 303, 66 L. Ed. 619 (1922); *United States v. Warren*, 453 F.2d 738 (2d Cir. 1972), Cert. denied, 406 U.S. 944, 92 S.Ct. 2040, 32 L.Ed.2d 331 (1972); *United States v. Brandenburg*, 155 F.2d 110 (3d Cir. 1946).

87 *United States v. Abdallah*, 149 F.2d 219 (2d Cir. 1945), Cert. denied, 326 U.S. 724, 66 S.Ct. 29, 90 L.Ed. 429 (1945).

88 *Warren*, 453 F.2d 738; *White v. United States*, 399 F.2d 813 (8th Cir. 1968); *Brown v. United States*, 250 F.2d 745 (5th Cir. 1958), cert. denied, 356 U.S. 938, 78 S.Ct. 779, 2 L.Ed.2d 812 (1958); *Brandenburg*, 155 F.2d 110.

89 *Abdallah*, 149 F.2d 219.

90 *Warren*, 453 F.2d 738.

91 *Brandenburg*, 155 F.2d 110.

92 *United States v. Larson*, 507 F.2d 385 (9th Cir. 1974).

93 *United States v. Bartee*, 479 F.2d 484 (10th Cir. 1973); *United States v. Larson*, 507 F.2d 385. *United States v. Rosen*, 582 F.2d 1032 (5th Cir. 1978).

94 *In the Matter of The Medicine Shoppe* Fed. Reg. / Vol. 79, No. 191 / Thursday, October 2, 2014 / Notices 59504 to 59517.

95 The DEA's statistics reflect that the combination of these three drugs has the effect of heroin and is highly addictive. From the Pharmacist's Manual, USDOJ DEA. There were additional red flags, including missing prescriber signatures, missing patient addresses and DEA numbers that were missing or incorrect.

96 *See* Pet. Br. at 4. *The Medicine Shoppe v. Loretta Lynch, et al.* 14-223 (2014).

97 *Ibid.*

98 See Pet. Br. at 4.

99 *Ibid.*

100 *See Recommended Findings of Fact, Conclusions of Law and Decision of the Administrative Law Judge* to the DEA Deputy Administrator, Thomas M. Harrigan. (citing 21 U.S.C. § 824(a) & 21 U.S.C. § 823(f)). 79 Fed. Reg. 191 pgs. 59504-59517 – *In the Matter of The Medicine Shoppe*; Decision and Order (October 2, 2014).

101 *Id.* at 59505.

102 Pharmacy Reporting Form and Memo on Changes to Policy, *available at* http://nmms.org/news/2013/pharmacy-reporting-form-and-memo-changes-policy-go.

[103] http://ecfr.gov/cgi-bin/text-idx?node=se39.1.952_11.

[104] *See Gregory v. Ashcroft*, 501 U.S. 452, 461, (1991) (holding that states' police powers grant them exclusive authority to set licensing standards).

[105] *Supra* note 73.

[106] *See The Medicine Shoppe v. Loretta Lynch, et al.* 14-223 (2014) Pet. Br. at 4.

[107] *Moore*, 423 at 138-39.

[108] Medicare defines "medical necessity" as services or items reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. If Medicare or other payors determine that services were medically unnecessary after payment has already been made, they treat it as an overpayment and demand that the money be refunded, with interest. Moreover, if a pattern of such claims can be shown and the physician knows or should know that the services are not medically necessary, the physician may face large monetary penalties, exclusion from the federal healthcare programs, and criminal prosecution. Nancy W. Miller, Esq. "What is Medical Necsssity?" Physician's News Digest. August 2002. http://chiro.org/documentation/FULL/What_is_Medical_Necessity.html.

[109] *See Holiday CVS, L.L.C., d/b/a CVS Pharmacy Nos. 219 and 5195*, 77 Fed. Reg. 62,316, 62,340-41 (Oct. 12, 2012) (interpreting 21 C.F.R. § 1306.04(a) limiting a pharmacist's duty to determine the legitimacy of a prescription).

[110] *Ibid.*

[111] *The Medicine Shoppe*, 14-1223 Resp. Br. 10.

[112] *Ibid.*

[113] *The Medicine Shoppe*, 14-1223 Resp. Br. 10 (citing *Ralph J. Bertolino, d/b/a Ralph J. Bertolino Pharmacy*, 55 Fed. Reg. 4729, 455 Fed. Reg. 4729, 4730 (1990).

[114] http://texas-defense-lawyer.com/Articles/The-Medicine-Shoppe-v-DEA-14-1223-I.

[115] *Ibid.*

[116] *United States v. Morton Salt Co.*, 338 U.S. 632, 642–643 (1950).

[117] *Ibid.*

[118] http://kevinmd.com/blog/2012/04/future-medicine-aspiring-young-doctors.html.

[119] Advanced Practice Nurses' Use of Prescription Drug Monitoring Program Information, Steven D. LeMire, PhD; Sarah G. Martner; Cheryl Rising, RN, Journal for Nurse Practitioners. 2012;8(5):383.

[120] *Ibid.*

[121] This concern is evident from the "specific issues and questions that have been raised on a recurring basis by physicians [and pharmacists] who seek guidance on the subject of dispensing controlled substances for the treatment of pain." *Pharmacy Reporting Form and Memo on Changes to Policy on Good Faith Dispensing of Controlled Substances*, New Mexico Medical Society, May 2013. http://nmms.org/news/2013.

[122] *See United States v. Pawan Kumar Jain*, 2:14-cr-01261-RB, In the United States District Court, District of New Mexico, Las Cruces Division.

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MEDICARE ENROLLMENT: CMS's MOST POTENT PROGRAM INTEGRITY TOOL BECOMES EVEN STRONGER[1]

Jessica L. Gustafson, Esq.
Adrienne Dresevic, Esq.
The Health Law Partners, P.C.
Southfield, MI

Donald Romano, Esq.
Foley & Lardner LLP
Washington, DC

Introduction

The Centers for Medicare & Medicaid Services ("CMS") views its Medicare enrollment regulations as an essential program integrity tool, serving to protect the Medicare Trust Funds from fraud, waste and abuse. Recently, through regulation, CMS significantly expanded its authority to deny and revoke Medicare providers' and suppliers' Medicare billing privileges.[2] Although most or all providers and suppliers are familiar with the concept of exclusion from federal healthcare programs, there is less familiarity and (misplaced) less concern with revocations of Medicare billing privileges, although the practical effect can be largely the same. Many well-intended healthcare providers and suppliers easily could face Medicare revocation for overlooking seemingly minor administrative requirements that have strict compliance deadlines. Healthcare providers and suppliers and their legal counsel must acquaint themselves with the Medicare enrollment regulations and ensure compliance with them in order to withstand the enrollment scrutiny in today's healthcare regulatory environment.

Background

Section 1866(j) of the Social Security Act[3] was enacted as part of the Medicare Prescription Drug, Improvement, and Modernization Act ("MMA") of 2003.[4] This section of the law directed the Secretary of the Department of Health and Human Services ("HHS") to adopt a regulatory process related to Medicare enrollment. On April 21, 2006, CMS published a final rule implementing the MMA's provisions related to enrollment, setting forth requirements for providers and suppliers to obtain and maintain Medicare privileges (the "2006 Final Rule").[5] These requirements are codified in 42 C.F.R. Part 424, Subpart P. The intent of the 2006 Final Rule was "to protect beneficiaries and the Medicare Trust Funds by preventing unqualified, fraudulent, or excluded providers and suppliers from providing items or services to Medicare beneficiaries or billing the Medicare program or its beneficiaries."[6]

Since the 2006 Final Rule, Congress and CMS increasingly have relied on Medicare enrollment requirements as a tool to protect the integrity of the Medicare Trust Funds. Enacted on March 23, 2010, the Patient Protection and Affordable Care Act ("PPACA")[7] served, in part, to expand the Administration's focus on providers' and suppliers' compliance with Medicare enrollment regulations:

- Section 6401 of PPACA amended Section 1866(j) of the Social Security Act[8] to mandate increased scrutiny of new and existing providers' and suppliers' compliance with Medicare enrollment regulations. The level of scrutiny is based on providers' and suppliers' perceived risk of fraud, waste and abuse as determined by CMS. In compliance with PPACA's requirements, beginning on March 25, 2011, providers and suppliers were categorized into three levels of risk for fraud, waste and abuse: (1) limited, (2) moderate, and (3) high. Providers and suppliers perceived to have a "limited" categorical risk for fraud, waste and abuse are subject to the lowest level of scrutiny (e.g., physicians and non-physician practitioners, ambulatory surgical centers ("ASCs") and hospitals, among others);[9] providers and suppliers perceived to have a "high" categorical risk for fraud and abuse (i.e., newly-enrolling home health agencies ("HHAs") and newly-enrolling durable medical equipment, prosthetic and orthotic ("DME-POS") suppliers) are subject to the highest level of scrutiny.[10]
- Section 6402(d) of PPACA amended Section 1128(b) of the Social Security Act[11] to allow permissive exclusions and civil monetary penalties ("CMPs") for "[a]ny individual or entity that knowingly makes or causes to be made any false statement, omission, or misrepresentation of a material fact in any application, agreement, bid, *or contract to participate or enroll as a provider or supplier under a Federal health care program*… ."[12]

Following passage of PPACA, CMS and HHS' Office of Inspector General ("OIG") have taken additional steps to increase scrutiny and enforcement of providers' and suppliers' compliance with Medicare enrollment requirements. Highlighting these ever-increasing enforcement efforts:

- In its 2013, 2014, 2015 and 2016 Work Plans, the OIG identified providers' and suppliers' compliance with Medicare enrollment requirements as an area that will be subject to review, pursuant to Section 6401 of PPACA.[13]
- In early 2012, CMS adopted and implemented a National Fraud Prevention Program ("NFPP"), which streamlines CMS' benefit integrity efforts regarding both provider enrollment and claims payment. Relying on data mining, the NFPP integrates automated provider

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screening mechanisms during enrollment and predictive analytics in claims processing. As part of the NFPP, beginning in 2011 CMS began the process of revalidating the enrollments of all existing 1.5 million Medicare providers and suppliers. According to the most-recently available CMS data, "[f]rom May 2011 through the end of 2012, more than 400,000 providers were subject to the new screening requirements *and nearly 150,000 lost the ability to bill the Medicare Program* due to the [PPACA] requirements and other initiatives."[14]

- In the President's Fiscal Years 2015 and 2016 Budget Proposals, HHS proposed legislation to allow CMPs against providers and suppliers that fail to update their Medicare enrollment records.[15]
- On May 12, 2014, the OIG proposed regulatory changes to implement the statutory authority of PPACA providing for CMPs and permissive exclusion for "making false statements, omissions or misrepresentations in an enrollment application."[16]
- Most recently, on December 5, 2014, CMS published a final rule (the "2014 Final Rule")[17] expanding CMS's ability to deny and revoke Medicare providers' and suppliers' Medicare privileges.

CMS Final Rule (December 5, 2014) Enrollment Provisions

There are eight main provisions of the 2014 Final Rule related to Medicare enrollment. These provisions address the following: (1) Definition of enrollment; (2) Debts to Medicare; (3) Felony convictions; (4) Abuse of billing privileges; (5) Post-revocation submission of claims; (6) Effective date of billing privileges; (7) Effective date of re-enrollment bars; and (8) Corrective Action Plans ("CAPs").

Definition of Enrollment

Most healthcare physicians and non-physician practitioners enroll in Medicare to become eligible to obtain and maintain Medicare billing privileges. However, some physicians and non-physician practitioners are required to enroll in Medicare for the sole purpose of ordering or certifying items or services for Medicare beneficiaries. In July 2011, CMS made available CMS Form 855O, an enrollment application designed for those physicians and other non-physician practitioners who wish to enroll in Medicare exclusively for the purpose of ordering or certifying items or services for Medicare beneficiaries.[18]

Prior to publication of the 2014 Final Rule, CMS's definition of enrollment encompassed only actions related to becoming eligible to obtain Medicare billing privileges. The prior version of the regulation did not address those situations where a physician or non-physician practitioner had completed CMS Form 855O solely to become eligible to order or certify items or services for Medicare beneficiaries.[19]

Accordingly, the definition of "Enroll/Enrollment" (codified at 42 C.F.R. Section 424.502) was revised as follows (revisions identified in *italics*):

> *Enroll/Enrollment* means the process that Medicare uses to establish eligibility to submit claims for Medicare covered items and services, *and the process that Medicare uses to establish eligibility to order or certify Medicare covered items and services*. The process includes:
>
> (1) Identification of a provider or supplier;
>
> (2) *Except for those suppliers that complete the CMS-855O form, CMS-identified equivalent, successor form or process for the sole purpose of obtaining eligibility to order or certify Medicare covered items and services*, validating the provider or supplier's eligibility to provide items or services to Medicare beneficiaries;
>
> (3) Identification and confirmation of the provider or supplier's practice location(s) and owner(s); and
>
> (4) *Except for those suppliers that complete the CMS-855O form, CMS-identified equivalent, successor form or process for the sole purpose of obtaining eligibility to order or certify Medicare covered items and services*, granting the Medicare provider or supplier Medicare billing privileges.[20]

Corresponding revisions to the definition of "Enroll/Enrollment" were made to 42 C.F.R. Section 424.510 regarding the "Requirements for enrolling in the Medicare program." In particular, 42 C.F.R. Section 424.510 (a) (3) was added, which states:

> *To be enrolled solely to order and certify Medicare items or services, a physician or non-physician practitioner must meet the requirements specified in paragraph (d) of this section except for paragraphs (d)(2)(iii)(B), (d)(2)(iv), (d)(3)(ii), and (d)(5), (6), and (9) of this section.*[21]

Debts to Medicare

Prior to publication of the 2014 Final Rule, existing regulations permitted CMS to deny an enrollment application if the *owner* (as defined in 42 C.F.R. Section 424.502) of an applying provider or supplier or *physician* or *non-physician practitioner* applicant had an existing "overpayment" of $1,500 or more, which had not been repaid in full at the time of filing of an enrollment application.[22] The purpose of this authority was to address those situations in which an

owner of a provider or supplier incurred a debt to Medicare, exited the Medicare program, and thereafter attempted to re-enroll via another business entity.[23]

In the commentary to the 2014 Final Rule, CMS expressed concern that existing regulations did not go far enough. CMS's authority to deny enrollment applications did not extend to situations in which an enrolling provider or supplier had a Medicare debt other than an "overpayment." Additionally, CMS's denial authority did not address situations where an entity with which an enrolling provider, supplier or owner was affiliated incurred a Medicare debt and exited the Medicare program.[24]

In the 2014 Final Rule, CMS replaced the term "overpayment" with the term "debt" in 42 C.F.R. Section 424.530 (a) (6). The term "debt" was broadly defined to encompass any financial obligation to the Medicare program, regardless of how it was incurred or discovered.[25] Additionally, in the 2014 Final Rule, CMS expanded the authority to deny an applicant's enrollment application to include the situation where either the applicant or any entity (including a non-healthcare entity) related to the applicant has an outstanding debt.[26]

CMS illustrated this expanded denial authority as follows:

> Provider X is applying for enrollment in Medicare. Y owns 50 percent of X. Y was also a 20 percent owner of Supplier Entity Z, which was revoked from Medicare 12 months ago and currently has a large outstanding Medicare debt. The current version of § 424.530 (a) (6) could not be used to deny X's application because X's current owner (Y) does not have a Medicare debt. Rather, the entity with which Y was affiliated (Z) has the debt. However, under proposed § 424.530 (a) (6) (ii), and assuming the other criteria were met, X's application could be denied because X's owner was an owner of supplier (Z) that has a Medicare debt.[27]

In summary, in those situations where an enrolling provider, supplier or owner was previously the owner of a provider or supplier with a Medicare debt in existence at the time its Medicare enrollment was voluntarily terminated, involuntarily terminated, or revoked; the owner became unassociated with the debtor entity within one year of the debtor's termination or revocation; the debt was not repaid in full; and CMS determines that the debt poses an undue risk of fraud, waste or abuse, CMS may deny the enrollment application.[28] In determining whether an unpaid debt poses an undue risk of fraud, waste or abuse, CMS will consider the following five factors:

1. The amount of the Medicare debt.
2. The length and timeframe that the enrolling provider, supplier or owner thereof was an owner of the prior entity.
3. The percentage of the enrolling provider's suppliers or owner's ownership of the prior entity.
4. Whether the Medicare debt is currently being appealed.
5. Whether the enrolling provider, supplier or owner thereof was an owner of the prior entity at the time the debt was incurred.[29]

CMS assured providers and suppliers that it would "only exercise [its] discretion under § 424.530 (a) (6) in a careful and consistent manner."[30]

A Medicare applicant with an existing Medicare debt can avoid denial by repaying the debt in full or agreeing to a CMS-approved extended repayment schedule.[31]

The 2014 Final Rule did not also grant CMS authority to revoke an existing Medicare provider's or supplier's privileges for incurring a debt to CMS; however CMS noted that it may expand its regulations in the future to extend revocation authority to existing Medicare providers and suppliers.[32]

Felony Convictions

Prior to the effective date of the 2014 Final Rule, existing regulations (codified at 42 C.F.R. Sections 424.530 (a) (3) and 424.535 (a) (3)) permitted CMS to deny or revoke a Medicare provider's or supplier's Medicare enrollment if, within the ten (10) years preceding enrollment or revalidation, the provider, supplier or any of its owners was convicted of certain enumerated federal or state

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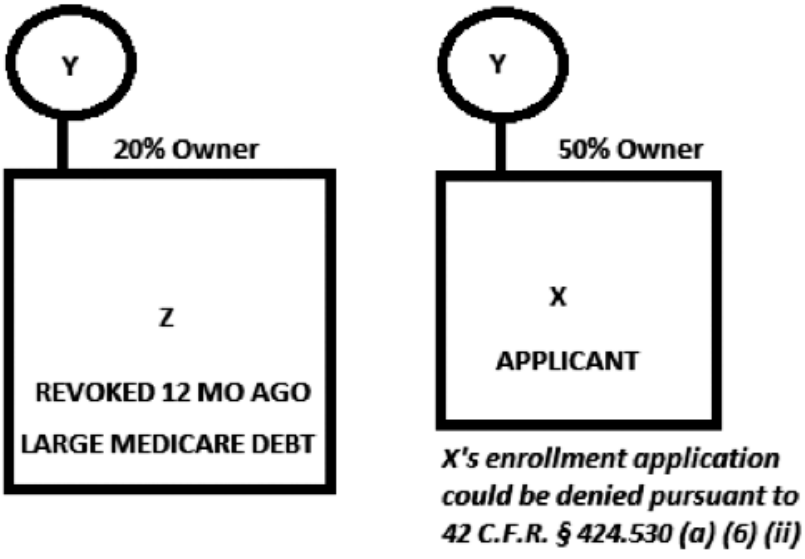

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felony offenses that CMS had determined to be detrimental to the best interests of the Medicare program and/or its beneficiaries.[33]

The 2014 Final Rule modified 42 C.F.R. Sections 424.530 (a) (3) and 424.535 (a) (3) to expand CMS's denial and revocation authority in four ways:

1. The 2014 Final Rule expanded CMS's denial and revocation authority to include situations in which a provider or supplier or any of its owners were convicted of *any* felony offense.[34] In so expanding its denial and revocation authority, CMS assured that "[w]e are not suggesting that every felony conviction will automatically result in such an action. Each case will be carefully reviewed on its own merits, and…we will act judiciously and with reasonableness in our determinations."[35] CMS declined to exclude certain felonies from denial or revocation consideration (e.g., felonies related to drugs and alcohol, traffic violations, and non-violent firearm felonies).[36] CMS further declined to adopt regulatory language limiting its denial and revocation authority to felonies meeting a given severity threshold; however, CMS did assert in its commentary that it would "only exercise [its] authority under § 424.530 (a) (3) or § 424.535 (a) (3) after consideration of the relative seriousness of the underlying offense and all of the circumstances surrounding the conviction."[37]
2. The 2014 Final Rule expanded CMS's denial and revocation authority to apply not only in cases where the provider, supplier and/or its owners was convicted of any felony, but also to apply where the provider's or supplier's managing employee(s) was convicted of a felony.[38] In adopting this regulatory change, CMS noted that "certain managing employees of a provider or supplier may have as much (if not more) day-to-day control as an owner."[39]
3. The 2014 Final Rule clarified its regulatory language to advise that it was permitted to deny or revoke a provider's, supplier's, owner's or managing employee's Medicare privileges if it had been convicted of a felony "within the preceding ten years."[40]
4. The 2014 Final Rule clarified that, for purposes of the enrollment regulations, the term "convicted" has the same definition as set forth within the "General Provisions" of Medicare's program integrity regulations, codified at 42 C.F.R. Section 1001.2.[41] Previously the term was not defined.

Abuse of Billing Privileges

Regulations existing prior to the implementation of the 2014 Final Rule, which are codified at 42 C.F.R. Section 424.535 (a) (8), permitted CMS to revoke a Medicare provider's or supplier's Medicare privileges based on a finding that the provider or supplier had abused its billing privileges as follows: "The provider or supplier submits a claim or claims for services that could not have been furnished to a specific individual on the date of service. These instances include but are not limited to the following situations: (A) Where the beneficiary is deceased. (B) The directing physician or beneficiary is not in the state or country when services were furnished. (C) When the equipment necessary for testing is not present where the testing is said to have occurred."

The 2014 Final Rule added 42 C.F.R. Section 424.535 (a) (8) (ii), which expanded CMS's revocation authority to encompass not only those situations where the services could not have been furnished as billed, but also those situations where CMS finds the provider or supplier to have "*a pattern or practice of billing for services that do not meet Medicare requirements such as, but not limited to, the requirement that the service be reasonable and necessary.*"[42]

In its proposed rule, CMS solicited comments regarding which factors ought to be considered in rendering a finding of abuse of billing privileges; whether any factors ought to be given greater or lesser weight than the others; and whether a minimum numerical or percentage threshold should be established for purposes of finding a "pattern and practice" of abusive billing.[43]

In the 2014 Final Rule, CMS left itself considerable discretion to find a "pattern and practice" of abuse of billing practices. In fact, CMS expressly declined to define the term "pattern and practice" in its regulations: "[W]e did not define 'pattern or practice' to maintain flexibility to address a variety of factual scenarios."[44] To avoid inconsistent application by various contractors, the 2014 Final Rule provided that "CMS, rather than our contractors, will make all determinations under § 424.535 (a) (8) (ii) and will consistently apply the criteria."[45]

According to the 2014 Final Rule, CMS will consider the following six factors in determining whether a provider or supplier has abused its billing privileges:

1. *The percentage of claims denied.*[46] According to CMS, a finding of a pattern and practice of abuse of billing practices could include the situation where a provider or supplier was subject to a pre-payment review and received a "significant amount" of claim denials over time for failing to meet medical necessity requirements.[47] Providers and suppliers placed on pre-payment review, or which provide services or supplies subject to a pre-payment review demonstration, are well advised to pay even more careful attention to the documentation supporting their

claims. The repercussions for failing to do so are no longer limited to claim denials.

CMS's proposed rule solicited comments regarding whether a minimum numerical or percentage threshold should be established before CMS could justifiably find a "pattern and practice" of billing for services that fail to meet Medicare's requirements. However, in the 2014 Final Rule, CMS declined to adopt such a threshold. After considering the comments received, CMS concluded that "[N]umerical thresholds should not be established because we need the flexibility to address a myriad of scenarios."[48]

In calculating the percentage of claims denied, CMS will disregard any claim denials that have been fully (rather than partially) overturned on appeal, as well as those that have been finally and fully adjudicated (meaning that the appeals process has been exhausted or the deadline for filing an appeal has passed).[49]

2. *The reason(s) for the claim denials.*[50]
3. *Whether the provider or supplier had a history of "final adverse actions" as defined by 42 C.F.R. Section 424.502.*[51]
4. *The length of time over which the pattern continued.*[52]
5. *The duration of time the provider or supplier had been enrolled in Medicare.*[53]
6. *Any other information CMS deems relevant.*[54]

Although CMS solicited comments regarding whether there should be a set knowledge standard associated with a finding of abuse of billing privileges under this provision, e.g., reckless disregard or knew or should have known,[55] CMS declined to adopt a knowledge standard in the 2014 Final Rule (finding such a standard would be duplicative of existing authorities).[56]

There is no question that CMS has granted itself significant flexibility to revoke providers' and suppliers' Medicare privileges based on findings of abusive billing practices. CMS attempts to assuage providers' and suppliers' concerns related to perceived unbridled discretion through repeated assertions in the 2014 Final Rule that it will not abuse its discretion:

> We do not believe that our proposal is arbitrary or grants CMS unlimited discretion. To the contrary, and as the commenters noted, we were very clear in the preamble of the proposed rule that sporadic billing errors would not result in revocation under § 424.535 (a) (8) (ii). Although we did not define "pattern or practice" to maintain flexibility to address a variety of factual scenarios, we listed several factors that would be considered in our § 424.535 (a) (8) (ii) determinations and requested feedback regarding other potential factors. Additionally, not only will CMS (rather than its contractors) make all such determinations, but also § 424.535 (a) (8) (ii) will be applied only: (1) In situations where the behavior could not be considered sporadic; and (2) after the most careful and thorough consideration of the relevant factors. These points cannot be stressed enough….[57]We disagree that our proposal will have a chilling effect on health care. This rule will not affect providers that take seriously their responsibilities to submit valid claims and to seek clarification when there is confusion or disagreement involving applicable policies… .[58]
>
> … [T]his final rule is focused on providers who cannot or will not come into compliance with our payment requirements after repeated claim denials… . [W]e reiterate that not only will we make all determinations under § 424.535 (a) (8) (ii), but also that this provision will be applied in situations where the behavior was not sporadic in nature. We are focused on instances where the provider is engaged in an ongoing pattern of submitting noncompliant claims… .[59]
>
> We are neither attempting to impede patient care nor reduce the number of providers and suppliers. We believe most Medicare suppliers and providers are conscientious about submitting claims that meet Medicare requirements, and this rule will not affect that majority. Once again, we are merely attempting to address the problem of providers and suppliers with patterns of non-compliant claim submission. Providers and suppliers that are not engaged in a pattern or practice of non-compliant billing will not be adversely affected.[60]

Post-Revocation Submission of Claims

Prior to the effective date of the 2014 Final Rule, existing regulations (codified at 42 C.F.R. Section 424.535 (h)) limited revoked physician organizations', physicians', non-physician practitioners' and IDTFs' ability to submit claims for pre-revocation services rendered to 60 calendar days from the effective date of the revocation. Citing the need to protect the Medicare Trust Funds from potentially fraudulent future claims, CMS proposed to expand Section 424.535 (h) to require *all* revoked providers and suppliers to submit all claims for items and services rendered pre-revocation within 60 days of the effective date of the revocation. Revoked HHAs would be required to submit all claims within 60 days of the later of (1) the effective date of the revocation; or (2) the final date of the HHA's last payable episode of care.[61]

Very few comments were received in response to CMS's proposal. Accordingly, CMS's proposed revisions

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were finalized. As revised, the text of 42 C.F.R. Section 424.535 (h) states:

> (h) *Submission of claims for services furnished before revocation*. (1)(i) Except for HHAs as described in paragraph (h)(1)(ii) of this section, a revoked provider or supplier must, within 60 calendar days after the effective date of revocation, submit all claims for items and services furnished before the date of the revocation letter.
>
> (ii) A revoked HHA must submit all claims for items and services within 60 days after the later of the following:
>
> (A) The effective date of the revocation.
>
> (B) The date that the HHA's last payable episode ends.

Effective Date of Billing Privileges

Prior to the effective date of the 2014 Final Rule, 42 C.F.R. Section 424.520 (d) established that, for newly-enrolling physicians, non-physician practitioners, and physician and non-physician organizations, the effective date of their billing privileges would be the later of: (1) the date a Medicare enrollment application was filed, if that application was subsequently approved; or (2) the date an enrolled physician or non-physician practitioner first began furnishing services at a new practice location. Citing the need to ensure that the Medicare program is not billed for services when any provider or supplier does not meet Medicare's enrollment requirements, the 2014 Final Rule revised 42 C.F.R. Section 424.520 (d) to include ambulance suppliers. Providers and those suppliers that are subject to survey and certification requirements are not included in this revision because of CMS's determinations that such providers and suppliers undergo an "extensive, multi-layered review process" prior to enrolling in Medicare, and regulatory limitations exist on such providers' and suppliers' ability to back-bill (protecting the Medicare Trust Funds).[62]

Effective Date of Re-Enrollment Bar

When a Medicare provider's or supplier's, owner's or managing employee's privileges are revoked (for any reason other than failure to respond timely to a revalidation request or other request for information), a re-enrollment bar is instituted for a period of one to three years, based on the severity of the basis for revocation.[63]

Prior to the promulgation of the 2014 Final Rule, the effective date of any re-enrollment bar was *either* (1) 30 days after CMS or the CMS contractor mailed its revocation determination to the provider or supplier, or (2) the date that CMS or its contractor determined that a provider or supplier had been excluded for a federal exclusion or disbarment, felony conviction, license suspension or revocation, or if the practice location is found not to be operational.[64]

Due to concerns for those situations in which delays in updating databases with criminal convictions and licensure actions led to abbreviated periods of revocation, the 2014 Final Rule revised 42 C.F.R. Section 424.535 (c) to specify that *all* re-enrollment bars would begin 30 days after CMS or its contractor mails a revocation determination to a provider or supplier. CMS stated that by starting the re-enrollment bar period after the revocation letter is sent, instead of when the adverse action became effective (which may have occurred months before CMS became aware of it) the full period can be imposed.[65]

Limitation on The Use of Corrective Action Plans ("CAPs")

One of the most significant changes to the Medicare enrollment regulations contained in the 2014 Final Rule is the limitation CMS placed on providers' and suppliers' ability to submit a corrective action plan ("CAP") following a revocation of Medicare privileges. A CAP serves to establish that a Medicare provider or supplier has come into compliance with Medicare enrollment requirements and may lead to reinstatement of Medicare billing privileges,[66] negating the need to appeal the revocation determination.

Prior to the effective date of the 2014 Final Rule, providers and suppliers that received a Medicare revocation determination were permitted to submit a CAP, unless the revocation was based on 42 C.F.R. Sections 424.535 (a) (2), 424.535 (a) (3) or 424.535 (a) (5).[67] It is now CMS's position that "[g]enerally, we do not believe that providers and suppliers should be exonerated from failing to fully comply with Medicare enrollment requirements simply by furnishing a CAP."[68]

Therefore, CMS revised 42 C.F.R. Section 405.809 to add a new paragraph (a) (1), "*(a) A provider or supplier – (1) may only submit a corrective action plan for a revocation for noncompliance under § 424.535 (a) (1) of this chapter… .*"[69]

In particular, CMS addressed the scenario where a provider or supplier neglected to update its practice location. In concluding that permitting a provider or supplier to submit a CAP in this scenario would be inappropriate, CMS noted that "it is the provider or supplier's responsibility – as indicated on the CMS-855 forms that the provider or supplier completes and signs as part of the enrollment process – to report changes to CMS on a timely basis."[70]

In its commentary, CMS assured providers and suppliers that "we stress

that revocations are not imposed for trivial reasons. Each prospective revocation is carefully reviewed to ensure that there are legitimate grounds for taking such action and that the integrity of the Medicare program warrants it."[71] Despite this assurance, many providers and suppliers may perceive this regulatory change to potentially lead to draconian results.

Conclusion

It is ever-more important that providers and suppliers familiarize themselves with the CMS enrollment regulations and their timeframes to ensure compliance with all requirements. Despite CMS's statements that it will carefully review decisions involving revocation or other enrollment decisions to "ensure that there are legitimate grounds" for taking action against a provider or supplier, there appears to be numerous instances where it has used its broad authority to take severe action for seemingly minor administrative mistakes or oversight by a provider or supplier. For example, some providers and suppliers have experienced Medicare revocation due to episodic and inadvertent mistakes made by billing companies. Others have had their Medicare privileges revoked for failure to update an address of a practice location within 30 days. Even in 2011, when CMS first stepped up its focus on providers and suppliers and their compliance with CMS enrollment requirements, it was becoming increasingly important for attorneys representing healthcare clients to stay apprised of all changes in the Medicare enrollment process to be better equipped to protect their clients' interests. Now, given CMS's even stronger program integrity authority, attorneys representing providers and suppliers must be more diligent than ever in helping clients ensure compliance with the myriad of Medicare enrollment regulations.

Jessica L. Gustafson is a founding shareholder with the healthcare law firm of The Health Law Partners, P.C. Ms. Gustafson co-leads the firm's Recovery Audit (RAC) and Medicare appeals practice group, and specializes in a number of areas, including: Medicare, Medicaid and other payor audit appeals, healthcare regulatory matters, compliance matters, reimbursement and contracting matters. She is a member of the editorial board of the *ABA Health eSource*, the American Bar Association Health Law Section's online magazine. She can be reached at (248) 996-8510 or *jgustafson@thehlp.com*.

Adrienne Dresevic, Esq., is a Founding Shareholder of The Health Law Partners, P.C., a nationally recognized healthcare law firm with offices in Michigan and New York. Practicing in all areas of healthcare law, she devotes a substantial portion of her practice to providing clients with counsel and analysis regarding the Stark Law, Anti-Kickback Statute, and compliance related issues. Ms. Dresevic is a member of the American Bar Association Health Law Section's Council, which serves as the voice of the national health law bar within the ABA. Ms. Dresevic also serves as the ABA Health Law Section's Co-Chair of the Physicians Legal Issues Conference Committee, Vice Chair of the Programs Committee (Executive Leadership), and Vice Chair of the Sponsorship Committee. She is licensed to practice law in Michigan and New York, and can be contacted at *adresevic@thehlp.com*.

Donald H. Romano is Of Counsel to Foley & Lardner LLP, in the firm's Washington D.C. office. He counsels clients on Medicare reimbursement, healthcare litigation and regulatory compliance matters, particularly those pertaining to the Anti-Kickback Statute, the physician self-referral statute (Stark Law), HIPAA, and the Medicare enrollment regulations. He is also the editor of the American Bar Association's book *What is…Stark Law*. Prior to joining Foley & Lardner LLP, Mr. Romano was a partner in another D.C. based law firm, and prior to that had over 25 years of experience in the Department of Health and Services, including as a senior attorney in the Office of General Counsel, and as a Division Director in the Centers for Medicare & Medicaid Services ("CMS").

Mr. Romano is a frequent speaker and author on health law topics. He is a past chair of the American Bar Association Health Law Section's Interest Group on Fraud and Compliance, and a past vice-chair of the American Health Lawyers Association's Regulations, Accreditation and Payment Group. He is admitted to the bars of the District of Columbia, Maryland and Massachusetts. He can be reached at *DRomano@foley.com*.

Endnotes

1 This article supplements the article, "The Medicare Enrollment Process – CMS's Most Potent Program Integrity Tool," Adrienne Dresevic, Esq. and Donald Romano, Esq., *The Health Lawyer,* Vol 23, No. 4, April 2011.

2 The term "provider" (abbreviated from the statutory term "provider of services" is defined in 42 C.F.R. § 400.202 as including a hospital, a critical access hospital, a skilled nursing facility, a comprehensive outpatient rehabilitation facility, a home health agency, or a hospice that has in effect an agreement to participate in Medicare, or a clinic, a rehabilitation agency, or a public health agency that has in effect a similar agreement but only to furnish outpatient physical therapy or speech pathology services, or a community mental health center that has in effect a similar agreement but only to furnish partial hospitalization services. The term "supplier" is defined in § 400.202 as a physician or other practitioner, or an entity other than a provider, that furnishes healthcare services under Medicare.

"Supplier" is also defined as an independent laboratory, furnisher of portable X-ray services, physical therapist in independent practice, end stage renal disease ("ESRD") facility, rural health clinic, federally qualified health center ("FQHC"), chiropractor, or ambulatory surgical center. For purposes of the Medicaid program a "provider" encompasses both a provider of services and a

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supplier. Adding to the confusion, Congress and others sometimes (incorrectly) use the term "provider" in the context of Medicare to include both providers of services and suppliers. Providers are generally paid under part A of Medicare (although sometimes under part B), and suppliers are always paid under part B. There are other, important differences between the two, including in the context of survey and certification requirements (or lack thereof).

3 42 U.S.C. § 1395cc.

4 Pub. L. No. 108-173, § 936(a)(2).

5 71 Fed. Reg. 20754 (April 21, 2006).

6 *Id.*

7 Public Law 111-148, 124 Stat. 119, March 23, 2010.

8 42 U.S.C. § 1395cc(j).

9 The complete listing of providers and suppliers determined to have a limited risk for fraud, waste and abuse includes the following: (i) physician or non-physician practitioners; (ii) ASCs; (iii) Competitive Acquisition Program/Part B Vendors; (iv) ESRD facilities; (v) FQHCs; (vi) histocompatibility laboratories; (vii) hospitals, including critical access hospitals, Department of Veterans Affairs hospitals, and other federally-owned hospital facilities; and (viii) health programs operated by an Indian Health Program or an urban Indian organization. 42 C.F.R. § 424.518. *See also* Medicare Program Integrity Manual ("MPIM") (CMS Internet-Only Publication 100-08), Chapter 15, Section 15.19.2.1.

10 42 C.F.R. § 424.518. *See also* MPIM (CMS Internet-Only Publication 100-08), Chapter 15, Section 15.19.2.1. Providers and suppliers listed as those having a moderate risk for fraud, waste and abuse (and thus are subject to a moderate level of enrollment scrutiny) include (i) ambulance service suppliers; (ii) community mental health centers; (iii) comprehensive outpatient rehabilitation facilities; (iv) hospice organizations; (v) independent clinical laboratories; (vi) independent diagnostic testing facilities ("IDTFs"); (vii) physical therapists enrolling as individuals or as group practices; (viii) portable x-ray suppliers; (ix) revalidating HHAs and (x) revalidating DMEPOS suppliers. *Id.* The regulations provide for an upward adjustment to a provider's or supplier's risk category from limited or moderate to high under certain, specified circumstances, *see* 42 C.F.R. § 424.518(c)(3), but do not provide for a downward adjustment.

11 42 U.S.C. § 1320a-7(b).

12 Emphasis added.

13 *See* OIG Work Plan Fiscal year 2013, at p. 18, *available at* http://oig.hhs.gov/reports-and-publications/archives/workplan/2013/Work-Plan-2013.pdf; OIG Work Plan Fiscal Year 2014, at p. 27, *available at* http://oig.hhs.gov/reports-and-publications/archives/workplan/2014/Work-Plan-2014.pdf; OIG Work Plan Fiscal Year 2015, at p. 22, *available at* http://oig.hhs.gov/reports-and-publications/archives/workplan/2015/FY15-Work-Plan.pdf; and OIG Work Plan Fiscal Year 2016, at p. 25, *available at* http://oig.hhs.gov/reports-and-publications/archives/workplan/2016/oig-work-plan-2016.pdf.

14 2013 National Training Program, Module: 10, Medicare and Medicaid Fraud Prevention at p. 16, *available at* http://cms.gov/Outreach-and-Education/Training/CMSNationalTrainingProgram/Downloads/2013-Fraud-and-Abuse-Prevention-Workbook.pdf. *See also* Report to Congress Fraud Prevention System Second Implementation Year, June 2014, *available at* http://www.stopmedicarefraud.gov/fraud-rtc06242014.pdf (emphasis added).

15 *See* HHS FY 2015 Budget in Brief, *available at* http://hhs.gov/about/budget/fy2015/budget-in-brief/cms/program-integrity/index.html and HHS FY 2016 Budget in Brief, *available at* http://hhs.gov/about/budget/budget-in-brief/cms/program-integrity/index.html.

42 U.S.C. § 1320a-7a (a) (9) grants CMS the authority to impose CMPs against a provider or supplier that "knowingly makes or causes to be made any false statement, omission, or misrepresentation of a material fact in any application, bid, or contract to participate or enroll as a provider of services or a supplier under a Federal health care program (as so defined), including Medicare Advantage organizations under part C of subchapter XVIII of this chapter, prescription drug plan sponsors under part D of subchapter XVIII of this chapter, Medicaid managed care organizations under subchapter XIX of this chapter, and entities that apply to participate as providers of services or suppliers in such managed care organizations and such plans." As of the date of publication of this article, the statutory language has not been updated to reference a provider's or supplier's failure to update an enrollment application when/if changes occur.

16 79 Fed. Reg. 27080 (May 12, 2014). As of the date of publication of this article, a final rule has not been issued.

17 79 Fed. Reg. 72500 (December 5, 2014), effective February 3, 2015.

18 79 Fed. Reg. at 72501. *See also* MPIM, Ch. 15, § 15.16.1. Physicians and non-physician practitioners enrolling via the CMS-855O do not and will not send claims to a Medicare Administrative Contractor for the services they furnish. Examples of such physicians include, but are not limited to, physicians who are employed by the Department of Veterans Affairs, the Public Health Service, FQHCs, Rural Health Clinics, dentists, and pediatricians.

19 79 Fed. Reg. at 72501.

20 79 Fed. Reg. at 25018.

21 *See also* 79 Fed. Reg. at 72505. Each of the subsections excluded from applicability to physicians and non-physician practitioners completing a CMS Form 855O relate solely to the *billing privileges* of an enrolling provider or supplier.

22 79 Fed. Reg. at 72505 (emphasis added). *See also* MPIM, Ch. 15, § 15.13. 42 C.F.R. § 424.502 defines the term *owner* to include "any individual or entity that has any partnership interest in, or that has 5 percent or more direct or indirect ownership of the provider or supplier as defined in sections 1124 and 1124A(A) of the Act.

23 *Id.*

24 *Id.* at 72507.

25 *Id.* The preamble to the 2014 Final Rule is clear that CMS intends "debt" to encompass more than just an overpayment, but does not give any examples of "debts" that are not overpayments.

26 *Id. at 72505.* CMS did not include the enrolling entity's current managing employees, corporate officers, or directors within the scope of 42 C.F.R. § 424.530 (a) (6).

27 *Id.* at 72506.

28 42 C.F.R. § 424.530 (a) (6).

29 79 Fed. Reg. at 72509. *See also* 42 C.F.R. § 424.530 (a) (6) (ii).

30 *Id.*

31 42 C.F.R. § 424.530 (a) (6) (iii). *See also generally,* MPIM, Ch. 15, § 15.8.4.

32 79 Fed. Reg. at 72507.

33 71 Fed. Reg. at 20779. *See also* MPIM, Ch. 15, §§ 15.8.4. Examples included financial crimes, such as extortion, embezzlement, income tax evasion, making false statements, insurance fraud, and other similar crimes for which the individual was convicted.

34 *Id.*

35 79 Fed. Reg. at 72510.

36 *Id.*

37 *Id.*

38 *Id.*

39 *Id.*

40 *Id.* The previous language was "within the 10 years preceding enrollment or revalidation of enrollment." CMS proposed and finalized the language change because it said the previous language caused confusion as to how far back the 10-year period went.

41 *Id.* 42 C.F.R. § 1001.2 defines the term "Convicted" as follows:

(a) A judgment of conviction has been entered against an individual or entity by a Federal, State or local court, regardless of whether:

(1) There is a post-trial motion or an appeal pending, or

(2) The judgment of conviction or other record relating to the criminal conduct has been expunged or otherwise removed;

(b) A Federal, State or local court has made a finding of guilt against an individual or entity;

(c) A Federal, State or local court has accepted a plea of guilty or *nolo contendere* by an individual or entity; or

(d) An individual or entity has entered into participation in a first offender, deferred

adjudication or other program or arrangement where judgment of conviction has been withheld.

42 79 Fed. Reg. at 72513 (emphasis added). *See also* 42 C.F.R. § 424.535 (a) (8) (ii).

43 *Id*.

44 79 Fed. Reg. at 72514.

45 *Id*.

46 79 Fed. Reg. 72517 and 42 C.F.R. § 424.535 (a) (8) (ii) (A).

47 78 Fed. Reg. 25013 at 25022 (April 29, 2013), 79 Fed. Reg. at 72515.

48 79 Fed. Reg. at 72514. In a previous final rule implementing 42 C.F.R. § 424.535 (a) (8) (i), CMS similarly noted that it would limit its revocation authority to those situations in which abusive billing practices were clearly established. However, CMS concluded that abusive billing practices could be established by just three instances of billing errors. "We recognize the impact that this revocation has, and a revocation will not be issued unless sufficient evidence demonstrates abusive billing patterns. Accordingly, we will not revoke billing privileges under § 424.535 (a) (8) unless there are multiple instances, **at least three**, where abusive billing practices have taken place." (emphasis added). Note that the threshold of three instances to establish abusive billing practices was not adopted in the regulatory text; this threshold is found solely in the commentary to the final rule. 73 Fed. 36448, at 36455 (June 27, 2008).

49 79 Fed. Reg. at 72513.

50 79 Fed. Reg. 72517 and 42 C.F.R. § 424.535 (a) (8) (ii) (B). In some situations, providers and suppliers experience claim denials related to deficiencies in an ordering physician's documentation. Commenters requested that such claim denials not be included in determinations governing whether a provider or supplier has a pattern and practice of submitting claims that do not meet Medicare requirements. In the 2014 Final Rule, CMS declined to exclude these claims from such determinations, finding "[w]e believe it is the responsibility of the provider submitting the claim to ensure that all requirements – including, as necessary, proper and compliant supporting documentation – have been met prior to a claim's submission." *Id*.

51 79 Fed. Reg. 72517 and 42 C.F.R. § 424.535 (a) (8) (ii) (C). Pursuant to 42 C.F.R. § 424.504:

Final adverse action means one or more of the following actions:

(i) A Medicare-imposed revocation of any Medicare billing privileges.

(ii) Suspension or revocation of a license to provide healthcare by any State licensing authority.

(iii) Revocation for failure to meet DMEPOS quality standards.

(iv) A conviction of a Federal or State felony offense (as defined in §424.535(a)(3)(i) within the last 10 years preceding enrollment, revalidation, or re-enrollment.

(v) An exclusion or debarment from participation in a Federal or State healthcare program.

52 79 Fed. Reg. 72517 and 42 C.F.R. § 424.535 (a) (8) (ii) (D).

53 79 Fed. Reg. 72517 and 42 C.F.R. § 424.535 (a) (8) (ii) (E).

54 42 C.F.R. § 424.535 (a) (8) (ii) (F).

55 78 Fed. Reg. at 20523.

56 79 Fed. Reg. at 72516.

57 79 Fed. Reg. at 72514.

58 *Id.*

59 79 Fed. Reg. at 72515.

60 79 Fed. Reg. at 72516. Despite CMS's assurances that it will refrain from using its revocation authority only in situations where a pattern of non-compliance is established, it appears that some contractors continue to revoke billing privileges under section 424.535 (a) (1) (not in compliance with enrollment requirements) for failure to submit proper claims. The authors submit that section 424.535(a)(1) is not a valid basis for revoking billing privileges for claims errors, and that such revocations are inconsistent with the 2014 Final Rule. This position is consistent with the Departmental Appeals Board ("DAB") case of *Proteam Healthcare, Inc.*, Docket No. A-14-97, Decision No. 2658, September 28, 2015, which found that CMS's revocation of Proteam's billing privileges (after Proteam mistakenly included the identification number of the wrong physician on certain claims) was improper.

61 *See* 78 Fed. Reg. at 25023. *See also* 79 Fed. Reg. at 72520-72521.

Recent case law addressing the effective date of a revocation of billing privileges includes the following: *Better Living/Better Health LLC v. CMS*, HHS DAB, Appellate Division, Doc. No. A-15-19, Dec. No. 2634 (May 1, 2015), and *Med-Caire, Inc. v. CMS*, HHS DAB, Civil Remedies Division, Doc. No. C-15-227, Dec. No. CR3826 (May 1, 2015). In these cases, the ALJs revised the revocation effective date when CMS or its contractor attempted to retroactively revoke billing privileges without presenting factual or legal arguments supporting a retroactive revocation. Moreover, when CMS revised its regulations to allow a retroactive revocation in these limited situations, CMS was not allowed to apply the revocation retroactively when the facts that led to the revocation occurred before the January 1, 2010 effective date of the regulations at 42 C.F.R. § 424.535(g). *See Derm One, PLLC v. CMS*, HHS DAB, Appellate Division, Doc. No. C-11-29, Dec. No. CR2355 (Apr. 12, 2011) (concluding that "[a] federal agency cannot create a new rule and apply it retroactively unless that power is conveyed expressly by Congress," citing to *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 215 (1988)).

62 79 Fed. Reg. at 72521. In addition to providers, certain suppliers, such as portable X ray suppliers, rural health clinics, ASCs, and ESRD facilities must pass the certification process in order to participate in Medicare. *See* 42 C.F.R. § 488.1. "Certification" is defined as a determination made by the state survey agency that providers and suppliers are in compliance with the applicable conditions of participation, conditions for coverage, conditions for certification, or requirements." *Id.*

63 42 C.F.R. § 424.535 (c). *See* MPIM, Ch. 15 § 15.27.2.

64 79 Fed. Reg. at 72522.

65 *Id*.

66 79 Fed. Reg. at 72523.

67 42 C.F.R. § 424.535 (a) (2) grants CMS the authority to revoke a provider's or supplier's Medicare privileges due to its conduct, or that of any owner, managing employee, authorized or delegated official, medical director, supervising physician, or other healthcare personnel of the provider resulting in exclusion from any federal healthcare program.

42 C.F.R. § 424.535 (a) (3) grants CMS the authority to revoke a provider's or supplier's Medicare privileges based on any felony conviction against the provider or supplier, any of its owners or any managing employee.

42 C.F.R. § 424.535 (a) (5) authorizes CMS to revoke a provider's or supplier's Medicare privileges based on findings of non-compliance during an on-site review.

68 78 Fed. Reg. at 25025.

69 79 Fed. Reg. at 72523. Pursuant to 42 C.F.R. § 424.535 (a) (1):

(a) *Reasons for revocation*. CMS may revoke a currently enrolled provider or supplier's Medicare billing privileges and any corresponding provider agreement or supplier agreement for the following reasons:

(1) *Noncompliance*. The provider or supplier is determined to not be in compliance with the enrollment requirements described in this subpart P or in the enrollment application applicable for its provider or supplier type, and has not submitted a plan of corrective action as outlined in part 488 of this chapter. The provider or supplier may also be determined not to be in compliance if it has failed to pay any user fees as assessed under part 488 of this chapter.

(i) CMS may request additional documentation from the provider or supplier to determine compliance if adverse information is received or otherwise found concerning the provider or supplier.

(ii) Requested additional documentation must be submitted within 60 calendar days of request.

See also MPIM, Ch. 15, § 15.25.1.1.

70 79 Fed. Reg. at 72523.

71 79 Fed. Reg. at 72524.

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