I. Introduction

Citing to data from the Department of Defense (DOD), the Wall Street Journal reported in early February that TRICARE – the federal government payor for military health insurance – paid $1.75 billion in fiscal year 2015 for compounded drugs, including creams.\(^1\)

However, after recently conducting parallel federal and state investigations, investigators from various agencies (including the DOD, Department of Justice (DOJ), and HHS Office of Inspector General (OIG)) suspect that the majority of those bills are fraudulent. Indeed, due in part to the dearth of regulations pertaining to compounding pharmacies, as well as the rates at which federal payors (especially TRICARE) reimburse compounded drugs, the market for such drugs has, to this point, been rife with suspected fraud and abuse.

This article provides an overview of compounding pharmacies and will discuss recently uncovered alleged fraudulent schemes in the industry. Additionally, this article serves as a "what to look for" guide for healthcare attorneys advising their clients with regards to relationships between compounding pharmacies and prescribing physicians.

II. Background: Compounding Pharmacies and Compounded Drugs

According to the Food and Drug Administration (FDA), "compounding" is a practice whereby a pharmacist, physician, or other authorized professional under the supervision of a pharmacist or physician "combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient."\(^2\) Physicians may decide to prescribe compounded drugs over ordinary prescription medications for a variety of reasons. For example, a patient incapable of swallowing a pill may seek an alternative compounded medication in liquid form.

Although the FDA retains some authority over the operations of compounding pharmacies, most regulatory authority in this area remains with the individual state boards of pharmacy.\(^3\) Moreover, the compounded drugs themselves are not FDA-approved; unlike most other prescription medications, "FDA does not verify the safety, or effectiveness of compounded drugs."\(^4\)

Originally, Section 503A of the Food and Drug Administration Modernization Act of 1997 exempted compounded drugs from the FDA’s standard drug approval
requirements with the condition that compounded drug providers refrain from
advertising or promoting such drugs. However, after the Supreme Court ruled that
the advertising prohibition violated commercial speech rights under the First
Amendment, compounding pharmacies have continually engaged in such
promotional activities. Marketing blitzes over the Internet and through
telemarketers have generated booming sales of compounded drugs since the
Court’s 2002 decision, and promotional pitches for products such as compounded
scar and pain creams have targeted seniors, military personnel, and even
professional athletes.

Indeed, due to TRICARE’s high rates of reimbursement for compound medications,
TRICARE beneficiaries (i.e., military personnel and their families) have been
subjected to the most “extreme sales tactics,” according to the Military Times. Such
tactics have included “cold calls,” Craigslist searches for sales reps and customers,
solicitations inside military hospital pharmacies, and even food trucks set up
outside of military bases that promise free lunch to TRICARE beneficiaries who sign
up to receive compound medications.

III. Alleged Fraud in the Compounding Pharmacy Industry

Recent settlements and reported investigations of alleged fraud and abuse by
compounding pharmacies highlight the government’s increased level of scrutiny
over the industry. Although the extent of such allegedly fraudulent practices
reaches beyond the TRICARE program, fraudulent billings for compounded drugs
to TRICARE have received the bulk of the government’s attention. Data from the
Defense Health Agency (DHA, the arm of the DOD responsible for overseeing the
TRICARE program) shows that TRICARE’s costs for compounded drugs rose from $5
million in 2004 to $514 million in 2014. Both the DHA and the DOJ picked up this
surge and, upon investigation, federal authorities uncovered the allegedly
fraudulent schemes that serve as the impetus for the spike in costs.

These investigations, which are currently underway across several states and in
several U.S. Attorneys’ Offices, have honed in on potential false claims, kickback
arrangements, and even improper auto-refill programs. Although each
investigation has its own unique set of facts and circumstances, the typical
TRICARE scheme proceeds as follows: Using the aggressive marketing tactics
described above, pharmacy sales reps and others hired to promote compound
medications market these drugs directly to TRICARE beneficiaries. Patients may be
asked to fill out an online form with their TRICARE number included, or to simply
send their insurance information straight to the sales rep. The information is then
sent along to a physician, who writes a prescription and sends it to a compounding
pharmacy. According to the DOD, “[t]hese prescriptions may not be tailored to the
beneficiary’s needs, and sometimes the beneficiary never even meets or speaks to
a doctor before the pharmacy sends them the drug. Not only that, but often there
is little or no evidence that these products are safe or effective. . . .” Indeed, lack
of medical necessity and the failure to establish proper physician-patient
relationships served as the basis of the DOJ’s allegations of False Claims Act (FCA)
violations in two recent settlements with Florida compounding pharmacies.

Moreover, pharmacies across the country have billed TRICARE as much as $10,000
to $20,000 per prescription, despite the fact that the cost to the pharmacy to make
the drugs is only a fraction of the submitted cost. These high profit margins allow
compounding pharmacies to provide incentives and other kickbacks to physicians
for agreeing to write prescriptions. According to one Assistant U.S. Attorney in
Florida, such kickback arrangements have “involved doctors conducting sham
research studies and being paid ‘speaker fees’ in exchange for prescribing
medicine.” In the case of the most recent settlement in Jacksonville, Florida, the
four physicians involved allegedly received kickbacks in the form of profit
distributions after the pharmacy had been reimbursed. Indeed, to enhance
the scheme even further, these four physicians allegedly recruited other doctors to
write prescriptions in exchange for a share of the money. Investigations are
currently under way in other states, such as Mississippi and Texas.

IV. Avoiding Illegal Arrangements Between Compounding Pharmacies and
Prescribing Physicians

As healthcare attorneys well know, the Anti-Kickback Statute (AKS) makes it a
felony for anyone to offer, pay, solicit, or receive any form of remuneration in
exchange for the referral of federal healthcare program business. Thus, for
example, the AKS prohibits the payment or receipt of anything of value in exchange
for a physician writing a prescription for compounded medications, if claims for
those medications are submitted to a federal healthcare program. Any such claims
submitted to a federal healthcare program for reimbursement are therefore
“tainted” by the kickback and, because violations of the AKS serve as predicates to
FCA liability, those claims will also be considered “false” under the FCA, thereby
subjecting both parties to the alleged kickback scheme to treble damages, per-
claim penalties, and possible program exclusion in addition to potential criminal
liability.

That does not mean, of course, that any remuneration from a compounding
pharmacy to a prescribing physician automatically violates the AKS. First, the AKS
is an intent-based statute and, so long as no “one purpose” of the remuneration is
to induce referrals, there is no violation of the statute. Second, there are a
number of “safe harbors” to the AKS and, if a relationship falls under such a safe
harbor, there is no violation.

One common safe harbor that could apply to the compounding pharmacy-
prescribing physician relationship is the safe harbor for personal services and
management contracts. An example of a relationship between a compounding
pharmacy and a prescribing physician that might fall under this safe harbor is a
bona fide speaker program, wherein the pharmacy pays the physician to speak at
conferences and other events about the pharmacy’s products. If the requirements
of the personal services safe harbor are met (e.g., among other things, the
agreement is for at least one year, set out in writing, signed by the parties, covers
all of the services that the physician will provide to the pharmacy, the aggregate
compensation is set in advance and is consistent with fair market value and does
not take into account the volume or value of referrals), then such a relationship
would fall under the safe harbor and be exempted from potential AKS
liability. Accordingly, in order to avoid such potential liability, both physicians who
prescribe compounded drugs, on the one hand, and compounding pharmacies, on
the other hand, must carefully assess their relationships with one another to ensure
compliance with the AKS.

Moreover, even where the physician does not receive any financial gain from
writing prescriptions, the physician must remain wary of the fact that federal
healthcare programs only reimburse for “medically necessary” products and
services. Indeed, because healthcare providers must certify up front that all
products and services rendered were medically necessary, billing for medically
unnecessary services constitutes a false certification and therefore violates the
FCA. Thus, physicians who prescribe compounded drugs may further subject
themselves to FCA liability if they fail to establish the proper physician-patient
relationship necessary to determine whether the patient truly needs the specially-
made medications.
A 1999 Fraud Alert issued by the OIG pertaining to improper physician certifications in dealing with medical equipment suppliers and home health agencies parallels the relationship some physicians have with their compounding pharmacies. As the Fraud Alert states:

Unscrupulous suppliers and providers may steer physicians into signing or authorizing improper certifications of medical necessity. In some instances, the certification forms or statements are completed by [equipment] suppliers or home health agencies and presented to the physician, who then signs the forms without verifying the actual need for the items or services. In many cases, the physician may obtain no personal benefit when signing these unverified orders and is only accommodating the supplier or provider. While a physician’s signature on a false or misleading certification made through mistake, simple negligence, or inadvertence will not result in personal liability, the physician may unwittingly be facilitating the perpetration of fraud on Medicare by suppliers or providers. When the physician knows the information is false or acts with reckless disregard as to the truth of the statement, such physician risks criminal, civil, and administrative penalties.31

Thus, to avoid such liability, physicians must take care to ensure that each patient for whom a prescription is written is seen personally. Moreover, proper documentation of the visit and the patient’s medication needs will lower the chance that medical necessity is later questioned.32

V. Conclusion

The government continues to crack down on compounding pharmacies and prescribing physicians for allegedly fraudulent billing of TRICARE and other government payors, particularly as it relates to potentially improper relationships between those pharmacies and physicians under the AKS. Understanding the underlying schemes and the causes of the recent uptick in enforcement will greatly aide physicians and pharmacies in maintaining compliance.

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3 Id.

4 Id.
FDA.gov, “Information on Compounding,”
http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding (last visitec
March 20, 2016).

Thompson v. Western States Med. Ctr., 122 S. Ct. 1497 (2002). Importantly, the constitutional issue in
Thompson should not be confused with the constitutional issues that have arisen in off-label promotion cas
brought under the Food, Drug and Cosmetic Act. See, e.g., United States v. Caronia, 703 F.3d 149 (2d Ci
2012) (holding that off-label drug promotion was protected by First Amendment).

Professional athletes have not only been the target of these pitches, but companies have actually used
professional athletes in these pitches. Indeed, as noted in the Wall Street Journal, former NFL quarterback
Favre has promoted pain creams made by one of the Mississippi compounding pharmacies currently under
investigation. See Barrett, supra note 1.

For reasons that have not been made clear by the DOD, TRICARE typically reimburses compounded medic
at rates significantly higher than reimbursement paid by other payors such as Medicare or private insuranc
companies, thereby making the TRICARE program the primary target of recent fraudulent billing schemes
involving these medications.

Patricia Kime, Pharmacies push pricier drugs to Tricare users, Military Times (April 10, 2015),
tactics/25535291.

Although this particular scrutiny over potential fraud and abuse is relatively new, the compounding pharma
industry is certainly no stranger to government scrutiny in general. For example, in 2012 a large
Massachusetts-based compounding pharmacy came under scrutiny after a meningitis outbreak was linked l
drugs. See Toni Clarke and Aaron Pressman, Meningitis-linked firm sold drugs without requiring prescripti
idUSL5E8LD0CQ20121013. This led to a consumer alert from the FDA in December 2012 entitled “The Spe
Risks of Pharmacy Compounding.” (Available online at http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm107836.htm).

See Evan Sweeney, $300M spike in TRICARE monthly spending linked to compounded drugs, FierceHealth
(May 11, 2015), http://www.fiercehealthpayer.com/antifraud/node/31796 (“Similar spending spikes have
occurred among private insurance providers in recent years. In 2013, Harvard Pilgrim said they were [sic]
longer covering compounded medications because of cost and safety concerns. Last year, other payers suc
UnitedHealth Group and Blue Cross Blue Shield jumped on board.”).

See Dana Treen, $10 million settlement in Jacksonville prescription case part of $2 billion fraud probe, The
Florida Times-Union (Feb. 11, 2016), http://jacksonville.com/news/crime/2016-02-11/story/10-million-
settlement-jacksonville-prescription-case-part-2-billion.

See Thomas Sullivan, States Target Compounding Pharmacies over Claims to Military Health Program, Poli
and Medicine (Nov. 17, 2015), http://www.policiymed.com/2015/11/states-target-pharmacies-over-claims-
military-health-program.html.

See Treen, supra note 12; see also, Cheryl Pellerin, DoD Helps Protect Beneficiaries from Deceptive Pharm.

Pellerin, supra note 14.

DOJ Press Release, United States Announces New round of Compound Pharmacy Settlements Expected to
Result in More Than $30 Million in Fines and Repayments (Nov. 25, 2015), https://www.justice.gov/usao-
See id.; see also Barrett, supra note 1; Treen, supra note 12.


Id.

See Kevin Krause, North Texas pharmacy in federal probe is accused of paying kickbacks to doctors, Dallas Morning News (Feb. 5, 2016), http://www.dallasnews.com/investigations/20160205-north-texas-pharmacy-federal-probe-is-accused-of-paying-kickbacks-to-doctors, see also Barrett, supra note 1.

42 U.S.C. § 1320a-7(b).

Id. § 1320a-7(b).


The AKS safe harbors can be found at 42 C.F.R. § 1001.952. It should be noted that, unlike exceptions to Stark Law, which are mandatory (i.e., if a relationship triggers the Stark Law but does not fall squarely under one of the Stark exceptions, there is a violation regardless of intent), the AKS safe harbors are voluntary. Because the AKS is an intent-based statute, a relationship that falls outside of a safe harbor does not violate the statute unless the requisite intent is present.

42 C.F.R. § 1001.952(d).

Id.

For example, healthcare providers submit claims to Medicare and Medicaid on the CMS-1500 form, which requires the provider to certify that the services were "medically indicated and necessary to the health of the patient." A sample of the CMS-1500 form can be found at https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/CMS1500805.pdf.

See id.


Although not the focus of this article, it should be noted that the DOJ and OIG have, over the last year or so, increased their scrutiny of individual physicians. See, e.g., the "Yates Memo" (available at https://www.justice.gov/dag/file/769036/download). Now, instead of simply focusing on the corporate ent
with the "deep pockets," federal authorities will also take steps to punish individual physicians that violate healthcare rules and regulations and, therefore, attorneys that represent large healthcare corporations and those who represent individual physicians must be intimately aware of those rules and regulations and advise their clients accordingly.