



## **COMPOUNDING PHARMACY CRACKDOWN: NEW TRENDS IN GOVERNMENT ENFORCEMENT**

2016 saw a wave of new government crackdowns on healthcare fraud claims. While all government insurers are involved, TRICARE, a Federal health care program (*see* 42 U.S.C. § 1320a-7b(f)), is leading the charge. The new favorite targets of the government's investigations are compounding pharmacies. Armed with federal indictments, subpoenas, and civil investigative demands, governmental agencies are literally knocking on the door of these alternative pharmacy providers. Based on recently unsealed indictments against compounding pharmacies, physicians, and related representatives, these cases primarily involve alleged violations of the civil False Claims Act (31 U.S.C. §§ 3729–3733), presenting false claims for reimbursement (18 U.S.C. § 287) and the Anti-Kickback statute (42 U.S.C. 1320a-7b(b)), and claims for conspiracy to commit health care fraud (18 U.S.C. § 1349 (18 U.S.C. § 1347)).

While some violations appear to be the result of intentional schemes to defraud the government and private payors, others derive from a lack of understanding about what may constitute a violation under an increasingly complex scheme of civil and criminal statutes. Accordingly, the following overview describes each violation separately and provides examples of potentially prohibited conduct based on recently unsealed federal indictments.

### **A. False Claims Act (31 U.S.C. §§ 3729–3733)**

The False Claims Act (the “FCA”) imposes liability on persons and companies (typically federal contractors) who defraud governmental programs. More specifically, the FCA establishes civil liability for the following:

1. Knowingly presenting, or causing to be presented, a false claim for payment or approval;
2. Knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim;
3. Conspiring to commit any violation of the False Claims Act;
4. Falsely certifying the type or amount of property to be used by the government;

5. Certifying receipt of property on a document without completely knowing that the information is true;
6. Knowingly buying government property from an unauthorized officer of the government; and
7. Knowingly making, using, or causing to be made or used a false record to avoid, or decrease an obligation to pay or transmit property to the government.

*See* 31 U.S.C. §§ 3729–3733.

Defendants found to have violated the FCA are liable to the government for a civil penalty of not less than \$5,000 and not more than \$10,000, per violation, plus three times the amount of damages the government sustains. Therefore, if a defendant received \$100 from TRICARE for a single prescription in violation of the FCA, the defendant would be liable for \$400 in damages (\$100 for the original damages + \$300 [three times the original damages]).

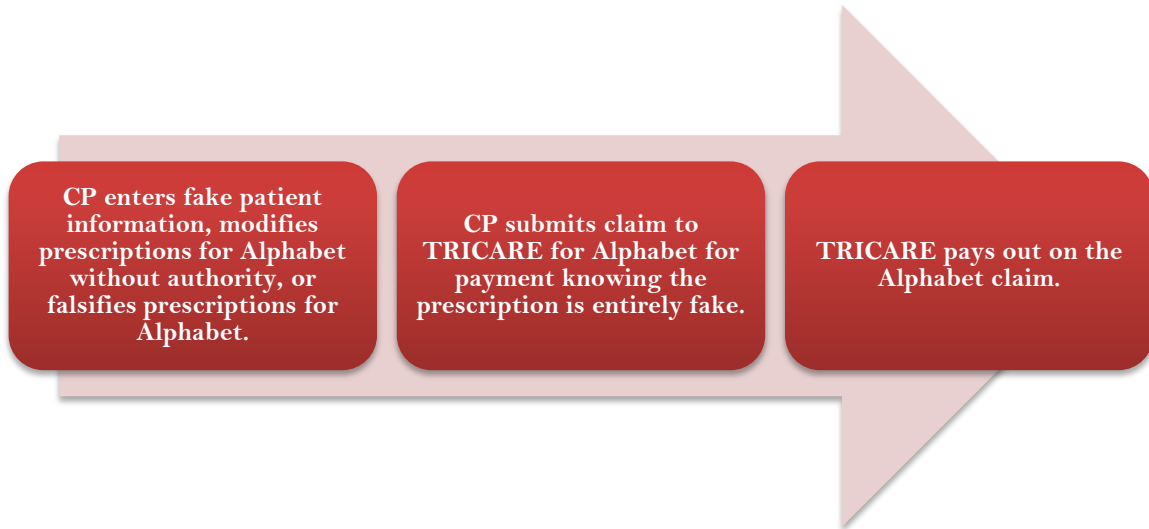
In the compounding pharmacy context, violations of the FCA typically occur when a defendant submits a claim to TRICARE for a prescription that is false, medically unnecessary, or constitutes a claim not backed by an authorized prescription.<sup>1</sup> Common scenarios of prohibited conduct are visualized below using the hypothetical pharmacy called “CP” and a prescription for the fake pain cream called “Alphabet.”

#### **SCENARIO 1: ENTIRELY FALSE CLAIMS**

In Scenario 1, the compounding pharmacy fabricates the entire transaction in order to get payment on the claim. This scenario is the most flagrant and clear cut violation of the FCA.

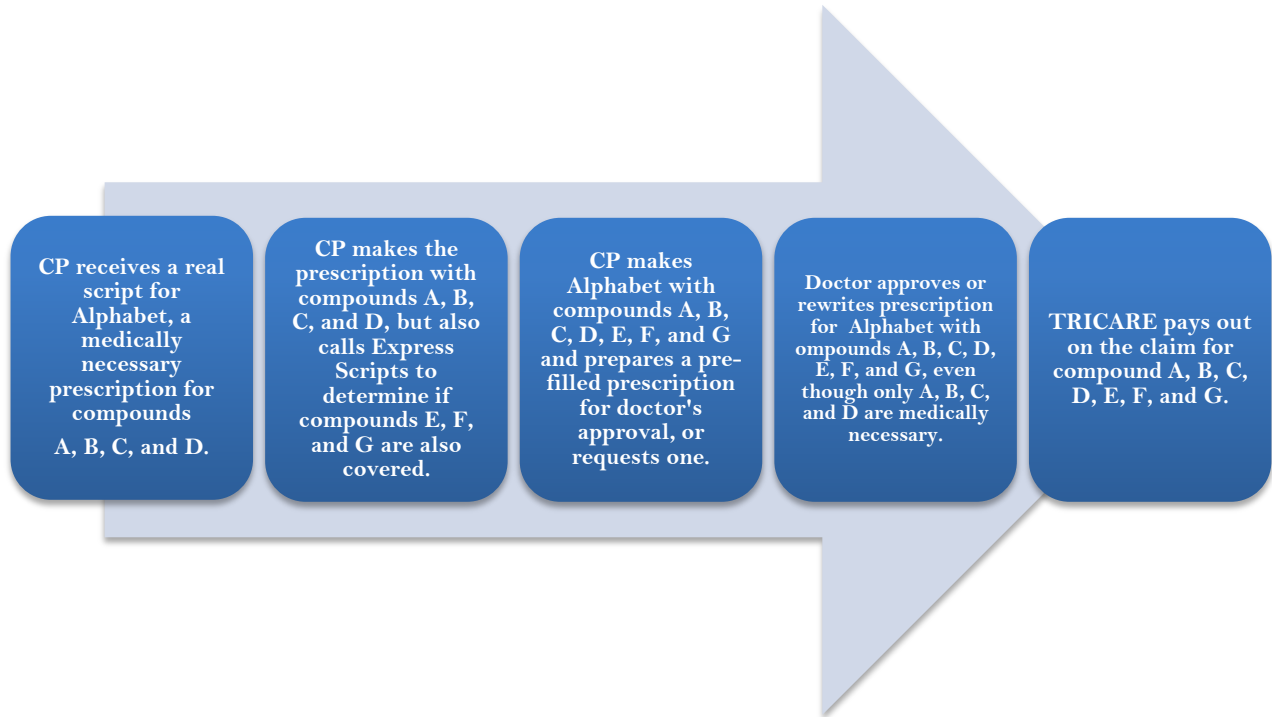
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<sup>1</sup> Note that the scenarios that follow are specific to trends in compound pharmacy cases, and are not the only situations in which liability may be assessed.



### **SCENARIO 2: MEDICALLY UNNECESSARY CLAIMS**

In Scenario 2, the compounding pharmacy has a real prescription for a real patient, but modifies the prescription for the sole purpose of increasing the reimbursement from TRICARE. The problematic part of this situation is that the pharmacy technicians, not the doctors, are creating compounds that contain medically unnecessary ingredients in order to drive up the cost of the prescription. While the doctors may later approve the prescription, it still likely contains medically unnecessary compounds – a violation in itself – and also raises red flags that the doctor may be getting a kickback to authorize the prescriptions. This scenario is less flagrant than Scenario 1, but still may constitute violations of the FCA and the Anti-Kickback Statute (see below).



### RELATED SCENARIOS TO CONSIDER

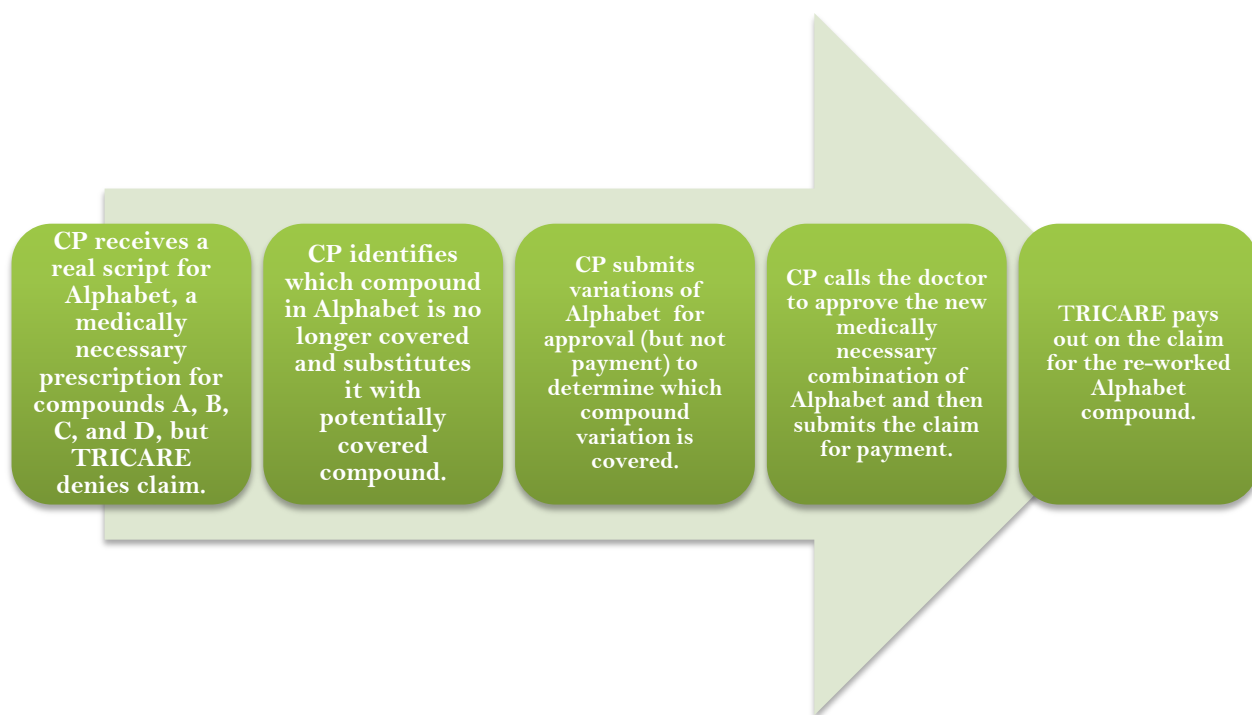
In addition to the typical scenarios visualized above, issues can arise when TRICARE and Express Scripts begin to drop coverage for a previously covered compound. For instance, in order to assist their customers in continuing to pay the least for medically necessary compounds, the pharmacies identify the ingredient no longer covered and attempt to substitute it with a covered alternative that has the same or similar effects. In attempting to determine coverage of an alternative compound, pharmacies may violate the Act if they submit claims for various combinations without first obtaining a new prescription for that particular combination from the doctor. Even if pharmacies submit probative claims exclusively to determine what compounds are covered – and not to obtain payment – the Act explicitly prohibits false or fraudulent claims submitted for payment *or approval*. 31 U.S.C. § 3729 (a)(1)(A). Thus, submitting various claims for approval to identify which compounds are covered may constitute a violation under the text of the law. Depending on the specific facts, however, this scenario may prove more defensible.

For example, if TRICARE never pays out for a probative claim, then (a) the “probative claim” may not be a “claim” subject to the FCA (*see* 31 U.S.C. § 3729(b)(2) defining a “claim” as a request or demand for money or property), and (b) there are no damages to the government

and therefore no civil penalty to pay. Additionally, Express Scripts itself is vague as to whether probative claims are prohibited; indeed, it may even promote them. Express Scripts' website states in its Frequently Asked Questions section entitled "How do I know if my compound drug is covered":

Compounds have multiple ingredients within them and coverage is evaluated for each individual ingredient. Therefore, the best way to determine if your compound prescription is covered is to request that your pharmacist process the claim electronically. The Express Scripts system will return coverage information real-time back to your pharmacist.

Quoted from: [https://www.express-scripts.com/TRICARE/faq/compound\\_drugs.shtml](https://www.express-scripts.com/TRICARE/faq/compound_drugs.shtml).



## B. False, Fictitious or Fraudulent Claims for Reimbursement (18 U.S.C. § 287)

The Federal "False, fictitious or fraudulent claims" statute imposes criminal liability on persons and companies who defraud governmental programs through the submission – whether paid or not – of false claims for reimbursement under a federal health care program. This criminal statute mirrors the FCA and carries a penalty of up to five years in prison plus a

fine. Like the FCA, the statute punishes a defendant who “makes or presents. . . any claim. . . knowing such claim to be false, fictitious, or fraudulent.”

In the compounding pharmacy context, acts that constitute a violation of the FCA likely constitute a violation of the criminal statute.

### **C. Federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b))**

The federal Anti-Kickback Statute is a criminal statute which makes it illegal for anyone to solicit, receive, offer, or pay remuneration in exchange for referring patients to receive certain services that are paid for by the government. The 2010 Patient Protection and Affordable Care Act (the “ACA”) changed the language of the Anti-Kickback Statute to provide that claims submitted in violation of the statute automatically constitute false claims for purposes of the FCA (31 U.S.C. §§ 3729–3733). Further, the new language of the statute provides that “a person need not have actual knowledge...or specific intent to commit a violation,” eliminating – or severely limiting – a provider’s ability to successfully argue they did not know they were violating the FCA because they were unaware of the Anti-Kickback Statute.

In the compounding pharmacy context, the government commonly alleges the defendants paid TRICARE beneficiaries for obtaining and filling prescriptions for compounded drugs, usually in the form of pain creams. One recent case against a Dallas-based compound pharmacy alleged a \$250 kickback to beneficiaries per prescription. *United States v. Richard Cesario, et al.*, Case No. 3:16-CR-060-M, Superseding Indictment at ¶ 25. As cover for paying patients to fill prescriptions at their pharmacies, compounding pharmacies have attempted to classify the payments to the patients as some other form of payment. For instance, in the *Cesario* case, the defendants allegedly disguised the payments to the TRICARE beneficiaries as “grants” for participating in fake medical studies called the “Patient Safety Initiative.” *Id.* at ¶ 26.

In addition to paying beneficiaries, the government frequently alleges compounding pharmacies paid prescribing physicians for each compound prescription they wrote. As part of this scheme, compounding pharmacies hired “pharmacy technicians,” who were unlicensed pharmaceutical trainees who would receive referrals from marketers in the area. The pharmacy technicians would use the information from the marketers to fill our prescriptions for compound medications and then contact Express Scripts to determine whether TRICARE

would cover the formulations and, if so, how much TRICARE would pay for each prescription. Based on Express Scripts' response, the pharmacy technicians would adjust the formulation of the prescriptions and repeat the process until they found the most profitable formulation without, allegedly, any medical necessity for the prescription. Once the highest-paying formulation was determined, the pharmacy technicians would send the patient's information and pre-filled prescriptions to the physicians for approval.

In addition to paying beneficiaries and physicians, the government alleges that compounding pharmacies paid employees kickbacks based on a percentage of the gross revenue of the pharmacy for the claims submitted to TRICARE. While bona fide employees of a pharmacy are excluded from liability under this statute (*see* 42 U.S.C. § 1320a-7b(b)(3)(B)), the recent indictments allege the employees were not actually employed by the compounding pharmacy, but rather by one of the non-pharmacy defendants. Typically, these bonuses to non-bona fide employees were disguised as employee wages paid by a co-defendant.

**D. Conspiracy to Commit Health Care Fraud (18 U.S.C. § 1349, 18 U.S.C. § 1347)**

Conspiracy to commit health care fraud requires that the defendants devise and execute a scheme to defraud a health care benefit program.

In the compounding pharmacy context, the government typically alleges pharmacies, pharmacists, healthcare representatives, and healthcare beneficiaries, *i.e.* individual patients, conspired to defraud TRICARE by making and receiving payments in connection with the prescription of compounded drugs to TRICARE beneficiaries. These payments are often alleged to include: (a) payments to TRICARE beneficiaries in exchange for filling prescriptions for compounded drugs; (b) payments to physicians in exchange for prescribing compounded drugs to TRICARE beneficiaries; and (c) payments to marketers in exchange for referrals of TRICARE beneficiaries and their prescriptions for compounded drugs. Acts that would constitute violations of the statutes addressed above, even if not carried out, form the basis for the government's conspiracy allegations in the compound pharmacy context.

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Bell Nunnally has provided legal defense to compound pharmacies, and their owners, officers, and individual employees. The circumstances of your situation are unique and may not



be covered by this overview. For further information, or to schedule a consultation, please contact Jeff Ansley, David Webster, or Greg Kelminson at Bell Nunnally.

Authored By Jeff Ansley and David G. Webster, Esq.