UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

Case No. 18-20561-CR-ALTONAGA/GOODMAN

18 U.S.C. § 1349
18 U.S.C. § 982(a)(7)

UNITED STATES OF AMERICA

vs.

ASCANIO SERNA,

Defendant.
_____/

INFORMATION

The United States Attorney charges that:

GENERAL ALLEGATIONS

At all times material to this Information:

The Medicare Program

1. The Medicare Program ("Medicare") was a federally funded program that provided free or below-cost health care benefits to certain individuals, primarily the elderly, blind, and disabled. The benefits available under Medicare were governed by federal statutes and regulations. The United States Department of Health and Human Services through its agency, the Centers for Medicare and Medicaid Services ("CMS"), oversaw and administered Medicare. Individuals who received benefits under Medicare were commonly referred to as Medicare "beneficiaries."

2. Medicare programs covering different types of benefits were separated into different program "parts." Part D of Medicare (the "Medicare Part D Program" or "Part D") subsidized the costs of prescription drugs for Medicare beneficiaries in the United States. The Medicare Part D

Program was enacted as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and went into effect on January 1, 2006.

3. In order to receive Part D benefits, a beneficiary enrolled in a Medicare drug plan. Medicare drug plans were operated by private companies approved by Medicare. Those companies were often referred to as drug plan "sponsors." A beneficiary in a Medicare drug plan could fill a prescription at a pharmacy and use his or her plan to pay for some or all of the prescription.

4. A pharmacy could participate in Part D by entering a retail network agreement directly with a plan or with one or more Pharmacy Benefit Managers ("PBMs"). A PBM acted on behalf of one or more drug plans. Through a plan's PBM, a pharmacy could join the plan's network. When a Part D beneficiary presented a prescription to a pharmacy, the pharmacy submitted a claim either directly to the plan or to a PBM that represented the beneficiary's Medicare drug plan. The plan or PBM determined whether the pharmacy was entitled to payment for each claim and periodically paid the pharmacy for outstanding claims. The drug plan's sponsor reimbursed the PBM for its payments to the pharmacy.

5. A pharmacy could also submit claims to a Medicare drug plan to whose network the pharmacy did not belong. Submission of such out of network claims was not common and often resulted in smaller payments to the pharmacy by the drug plan sponsor.

6. Medicare, through CMS, compensated the Medicare drug plan sponsors. Medicare paid the sponsors a monthly fee for each Medicare beneficiary of the sponsors' plans. Such payments were called capitation fees. The capitation fee was adjusted periodically based on various factors, including the beneficiary's medical conditions. In addition, in some cases where a sponsor's expenses for a beneficiary's prescription drugs exceeded that beneficiary's capitation fee, Medicare reimbursed the sponsor for a portion of those additional expenses.

7. Medicare was a "health care benefit program," as defined by Title 18, United States Code, Section 24(b), that affected commerce, and as that term is used in Title 18, United States Code, Section 1347.

8. Express Scripts Incorporated ("Express Scripts") and Caremark LLC d/b/a CVS/Caremark ("CVS/Caremark") were Medicare drug plan sponsors

Privately Insured Drug Plans

9. Commercial insurance companies, employers, and private entities offered drug plans which were also administered and operated by PBMs. A beneficiary in a privately insured drug plan could fill a prescription at a pharmacy and use his or her plan to pay for some or all of the prescription.

10. A pharmacy could participate in a privately insured drug plan by entering an agreement with one or more PBMs acting on behalf of a privately insured plan. When a privately insured beneficiary presented a prescription to a pharmacy, the pharmacy submitted a claim to a PBM that represented the beneficiary's privately insured drug plan. The plan or PBM determined whether the pharmacy was entitled to payment for each claim and periodically paid the pharmacy for outstanding claims. The drug plan's sponsor reimbursed the PBM for its payments to the pharmacy.

11. Express Scripts, OptumRX, Inc. ("OptumRX"), CVS/Caremark, MedImpact Healthcare Systems, Inc. ("MedImpact"), and Catamaran Corporation ("Catamaran") were each a "health care benefit program," as defined by Title 18, United States Code, Section 24(b), that affected commerce, and as that term is used in Title 18, United States Code, Section 1347.

The TRICARE Program

12. TRICARE was a health care program of the United States Department of Defense ("DOD") Military Health System that provided coverage for DOD beneficiaries worldwide, including active duty service members, National Guard and Reserve members, retirees, their families, and survivors. Individuals who received health care benefits through TRICARE were referred to as TRICARE beneficiaries. The Defense Health Agency ("DHA"), an agency of the DOD, was the military entity responsible for overseeing and administering the TRICARE program.

13. TRICARE was a "health care benefit program," as defined by Title 18, United States Code, Section 24(b), that affected commerce, and as that term is used in Title 18, United States Code, Section 1347.

14. TRICARE was a "health care benefit program," as defined by Title 42, United States Code, Section 1320a-7b(t), that affected commerce, and as that term is used in Title 42, United States Code, Section 1320a-7b(b).

15. TRICARE provided coverage for certain prescription drugs, including certain compounded drugs, that were medically necessary and prescribed by a licensed medical professional. Express Scripts administered TRICARE's prescription drug benefits.

16. TRICARE beneficiaries could fill their prescriptions through military pharmacies, TRICARE's home delivery program, network pharmacies, and non-network pharmacies. If a beneficiary chose a network pharmacy, the pharmacy would collect any applicable co-pay from the beneficiary, dispense the drug to the beneficiary, and submit a claim for reimbursement to Express Scripts, which would in turn adjudicate the claim and reimburse the pharmacy directly or through a Pharmacy Services Administrative Organization ("PSAO"). To become a network pharmacy, a

pharmacy agreed to be bound by, and comply with, all applicable State and Federal laws, specifically including those addressing fraud, waste, and abuse.

Compounded Drugs Generally

17. In general, "compounding" is a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug or multiple drugs to create a drug tailored to the needs of an individual patient. Compounded drugs are not approved by the U.S. Food and Drug Administration ("FDA"); that is, the FDA does not verify the safety, potency, effectiveness, or manufacturing quality of compounded drugs. The Florida State Board of Pharmacy regulates the practice of compounding in the State of Florida. However, the ingredients in compounded drugs may be FDA approved individually.

18. Compounded drugs may be prescribed by a physician when an FDA-approved drug does not meet the health needs of a particular patient. For example, if a patient is allergic to a specific ingredient in an FDA-approved medication, such as a dye or a preservative, a compounded drug can be prepared excluding the substance that triggers the allergic reaction. Compounded drugs may also be prescribed when a patient cannot consume a medication by traditional means, such as an elderly patient or child who cannot swallow an FDA-approved pill and needs the drug in a liquid form that is not otherwise available.

Copayments

19. Health care benefit payors – including private insurance companies, Medicare, and TRICARE – set copayments for many of the products and services they cover. Copayments are a portion of the cost of the product or service that must be paid by the patient or beneficiary.

20. Copayments are set based upon the payor's evaluation of the efficacy of the product or service, the cost of the product or service, and the availability of alternatives. Copayments are used to prevent or mitigate fraud in the case of expensive medications with limited evidence of effectiveness. That is, if a patient does not need or want a medication, they will be unlikely to pay a high copayment, the medication should not be dispensed, and the pharmacy should not make a claim to the payor.

21. Therefore, copayment collection requirements are prominently set forth in PBM contracts with pharmacies, and such requirements are material to PBMs, and PBMs audit pharmacies' copayment collection practices. A pharmacy's failure to collect copayments in good faith can result in the PBM's refusal to pay the claims and even termination of the contract with the PBM.

The Defendant, Related Individuals, and Entity

22. A.S.C. Pharmacy, Inc. ("ASC Pharmacy") was a Florida corporation that did business in Miami-Dade County, Florida. ASC Pharmacy was located at 3416 W. 84 Street, Suite 108, Hialeah, Florida. ASC Pharmacy purported to create and dispense compounded drugs.

23. Ascanio Serna ("Serna Jr.") was a resident of Miami-Dade County, Florida, and an owner, officer and director of ASC Pharmacy, and the son of defendant **ASCANIO SERNA**.

24. Co-Conspirator 1 was a resident of Broward County, Florida, and an owner, officer, director of ASC Pharmacy.

25. Defendant **ASCANIO SERNA** was a resident of Miami-Dade County, Florida, and an owner, officer, and director of ASC Pharmacy.

CONSPIRACY TO COMMIT HEALTH CARE FRAUD
(18 U.S.C. § 1349)

From in or around June 2013, through in or around March 2016, in Miami-Dade County, in the Southern District of Florida, and elsewhere, the defendant,

ASCANIO SERNA,

did willfully, that is, with the intent to further the object of the conspiracy, and knowingly combine, conspire, confederate, and agree with persons known and unknown to the United States Attorney, to commit offenses against the United States, that is, to knowingly and willfully execute a scheme and artifice to defraud a health care benefit program affecting commerce, as defined in Title 18, United States Code, Section 24(b), and to obtain, by means of materially false and fraudulent pretenses, representations, and promises, money and property owned by, and under the custody and control of, said health care benefit program, in connection with the delivery of and payment for health care benefits, items and services, in violation of Title 18, United States Code, Section 1347.

PURPOSE OF THE CONSPIRACY

It was a purpose of the conspiracy for the defendant and his co-conspirators to unlawfully enrich themselves by, among other things: (a) submitting and causing the submission of false and fraudulent claims to Medicare, TRICARE, and private health care benefit programs; (b) submitting and causing the submission of claims to Medicare, TRICARE, and private health care benefit programs based upon materially false and fraudulent pretenses, representations and promises; and (c) concealing the submission of false and fraudulent claims to Medicare, TRICARE and private health care benefit programs.

MANNER AND MEANS

The manner and means by which the defendant and his co-conspirators sought to accomplish the object and purpose of the conspiracy included, among other things:

26. **ASCANIO SERNA**, Serna Jr., Co-Conspirator 1, and other co-conspirators, caused the submission of false and fraudulent claims to Medicare, TRICARE, and private health care benefit programs for prescription medications, including compound creams, which were not medically necessary, not provided, and based upon the payment of illegal bribes and kickbacks.

27. **ASCANIO SERNA**, Serna Jr., Co-Conspirator 1, and other co-conspirators, falsely and fraudulently materially misrepresented to Medicare, TRICARE, and private health care benefit programs that ASC Pharmacy was making good faith attempts to collect patient copayments, which it was not.

28. As a result of the false and fraudulent claims, **ASCANIO SERNA**, Serna Jr., Co-Conspirator 1, and other co-conspirators, caused ASC Pharmacy to receive overpayments from Medicare, TRICARE, and private health care benefit programs of at least $3.4 million.

29. **ASCANIO SERNA**, Serna Jr., Co-Conspirator 1, and other co-conspirators, used the fraud proceeds received from ASC Pharmacy to benefit himself and others and to further the fraud.

All in violation of Title 18, United States Code, Section 1349.

FORFEITURE
(18 U.S.C. § 982(a)(7))

1. The allegations contained in this Information are re-alleged and incorporated by reference as though fully set forth herein for the purpose of alleging forfeiture to the United States of certain property in which the defendant, **ASCANIO SERNA,** has an interest.

2. Upon conviction of a violation of Title 18, United States Code, Section 1349, as alleged in this Information, the defendant shall forfeit to the United States any property, real or personal, that constitutes or is derived, directly or indirectly, from gross proceeds traceable to the commission of the offense, pursuant to Title 18, United States Code, Section 982(a)(7).

3. The property subject to forfeiture includes a money judgment in the amount of approximately $3,400,000 in United States currency, which sum represents the value of the gross proceeds traceable to the commission of the violation alleged in this Information.

4. If any of the property described above, as a result of any act or omission of any defendant:

a. cannot be located upon the exercise of due diligence;

b. has been transferred or sold to, or deposited with, a third party;

c. as been placed beyond the jurisdiction of the court;

d. as been substantially diminished in value; or

e. has been commingled with other property which cannot be divided without difficulty;

it is the intent of the United States to seek forfeiture of substitute property pursuant to Title 21, United States Code, Section 853(p), including the following:

1) one 2001 Vessel, 20'4" Cabin Motorboat, Hull No. LYGFA106F001;

2) one Performance Trailer, VIN: A0ZBP1919YPP75101; and

3) one 2014 Harley Davidson, VIN: 1HD1JDV15EB019888.

All pursuant to Title 18, United States Code, Section 982(a)(7), Title 28, United States Code, Section 2461(c), and the procedures set forth in Title 21, United States Code, Section 853.

BENJAMIN G. GREENBERG
UNITED STATES ATTORNEY
SOUTHERN DISTRICT OF FLORIDA

JOSEPH BEEMSTERBOER
DEPUTY CHIEF
CRIMINAL DIVISION, FRAUD SECTION
U.S. DEPARTMENT OF JUSTICE

DAVID A. SNIDER
TRIAL ATTORNEY
CRIMINAL DIVISION, FRAUD SECTION
U.S. DEPARTMENT OF JUSTICE