UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA

[UNDER SEAL], Plaintiffs, v. [UNDER SEAL], Defendants.	Civil Action No. _____ **COMPLAINT** **FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)** **JURY TRIAL DEMANDED**

DOCUMENT TO BE KEPT UNDER SEAL

DO NOT ENTER INTO PACER

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA

UNITED STATES *ex rel.* ALEX SPROULE and NICHOLAS FUHRMANN,

Plaintiffs,

v.

AURORA CARES LLC D/B/A TARA CARES; TARA PHARMACY SE, LLC; BIRMINGHAM NURSING AND REHABILITATION CENTER, LLC; BIRMINGHAM NURSING AND REHABILITATION CENTER EAST, LLC; NORTH HILL NURSING AND REHABILITATION CENTER, LLC; FLORENCE NURSING AND REHABILITATION CENTER, LLC; MOBILE NURSING AND REHABILITATION CENTER, LLC; ELBA NURSING AND REHABILITATION CENTER, LLC; NORTH MOBILE NURSING AND REHABILITATION CENTER, LLC; LAKELAND NURSING AND REHABILITATION CENTER, LLC; MANHATTAN NURSING AND REHABILITATION CENTER, LLC; LAKE CITY NURSING AND REHABILITATION CENTER, LLC.; DOUGLASVILLE NURSING AND REHABILITATION CENTER, LLC; JONESBORO NURSING AND REHABILITATION CENTER, LLC; and GEORGIA LONG TERM CARE AND CONSULTING, PC,

Defendants.

Civil Action No.:

COMPLAINT FOR VIOLATIONS OF THE FEDERAL FALSE CLAIMS ACT

FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)

JURY TRIAL DEMANDED

Qui tam Plaintiff-Relators Alex Sproule and Nicholas Fuhrmann, on behalf of the United States, for their Complaint against defendants Aurora Cares LLC d/b/a Tara Cares ("Tara Cares"); Tara Pharmacy SE, LLC ("Tara Pharmacy"); Birmingham Nursing and Rehabilitation Center, LLC; Birmingham Nursing and Rehabilitation Center East, LLC; North Hill Nursing and Rehabilitation Center, LLC; Florence Nursing and Rehabilitation Center, LLC; Mobile Nursing and Rehabilitation Center, LLC; Elba Nursing and Rehabilitation Center, LLC; North Mobile Nursing and Rehabilitation Center, LLC; Lakeland Nursing and Rehabilitation Center, LLC; Manhattan Nursing and Rehabilitation Center, LLC; Lake City Nursing and Rehabilitation Center, LLC; Douglasville Nursing and Rehabilitation Center, LLC; Jonesboro Nursing and Rehabilitation Center, LLC;, and Georgia Long Term Care and Consulting, PC (collectively, "Defendants"), allege as follows:

I. INTRODUCTION

1. The nation is experiencing a national public health emergency involving opioid abuse. The prescribing and dispensing of controlled substances, including opioid painkillers, without valid practitioner signatures and outside the course of professional practice exacerbates this crisis. This crisis impacts families and individuals as well as federal health care programs whose funds are used to pay for improperly dispensed controlled substances.

2. Defendants have fueled and profited from this epidemic by repeatedly dispensing medications, commonly opioids and other Schedule II narcotics, to vulnerable residents of long-term care facilities ("LTCFs") owned, operated, and/or controlled by Defendant Aurora Cares LLC d/b/a Tara Cares ("Tara Cares") without a valid prescription from a practitioner. The LTCFs owned, operated, managed, and/or controlled by Tara Cares are referred to in this Complaint as "Tara Cares LTCFs" or "Tara LTCFs."

3. Tara Pharmacy fills prescriptions for controlled substances for residents of Tara Cares LTCFs based only on requests from the LTCF, rather than dispensing the drugs upon valid prescriptions from practitioners. Mostly commonly, Tara Pharmacy fills orders submitted by Tara LTCFs in which the prescriber's name has been photocopied or otherwise mechanically copied. In other cases, Tara LTCF staff dispense drugs to patients from emergency kits provided by Tara Pharmacy without a required written order from the prescriber or oral communication between the prescriber and the pharmacy. In all of these cases and others, Tara Pharmacy dispenses drugs to LTCF residents, many of whom are federal health care program beneficiaries, without a valid prescription.

4. In addition, Tara Pharmacy dispenses non-controlled substances without valid prescriptions to elderly and disabled residents in Tara Cares nursing homes by allowing prescriptions that have expired or are out of authorized refills or are otherwise invalid, to be dispensed. Rather than ensuring that treating physicians are consulted to evaluate whether the dispensed drugs should be evaluated for refill or renewal, Tara Pharmacy simply assigns a new prescription number to an old prescription and "rolls over" the prescription in its "cycle fill" system.

5. Defendants' actions enable their nursing home staff to order drugs, and pharmacists to dispense those drugs, without confirmation that a practitioner has exercised his or her medical judgment about whether those drugs are being issued for a legitimate medical purpose and are appropriate in form, strength, and quantity for the resident.

6. As a result of these practices, Relators observed a rise in the use of prescription medication for sedation of elderly nursing home residents. The drugs included Depakote, Haldol, and Desyrel as well as antipsychotics such as Seroquel and Alzheimer's drugs including

Namenda and Aricept.

7. After dispensing drugs without a valid prescription, Defendants then cause claims for these drugs to be submitted to Medicare, Medicaid, and other federal health care programs.

8. Federal health care programs, including Medicare and Medicaid, do not cover drugs without a valid prescription. The orders that the Tara Cares LTCFs submit to Tara Pharmacy do not meet the requirements for a valid prescription under applicable federal and state laws and therefore are not payable under federal health care programs.

9. Many of the drug orders that Tara Pharmacy receives are for medications regulated as Schedule II narcotics under the Controlled Substances Act, 21 U.S.C. § 801 *et seq.* The Controlled Substances Act imposes strict requirements on prescriptions for Schedule II drugs, including that all non-emergency prescriptions contain the original signature of the prescribing physician. Medication orders that do not comply with the Controlled Substances Act are not "valid prescriptions" eligible for coverage under federal health care programs. The orders that the Tara Cares LTCFs submit to Tara Pharmacy for Schedule II drugs violate the Controlled Substances Act and therefore are ineligible for coverage under federal programs.

10. Defendants' "cycle fill" system also dispenses non-controlled medication to elderly residents of nursing homes without ensuring that the drugs are dispensed pursuant to valid prescriptions.

11. These reckless practices result in elderly residents receiving large numbers of medication including controlled substances and other mental health drugs with potentially serious health side effects in an elderly population.

12. At all relevant times, Defendants knew, within the meaning of the False Claims Act, that: (i) medications including controlled substances cannot be legally dispensed without a

valid prescription; (ii) Tara Cares LTCFs submits orders for medication, including controlled substances, without valid prescriptions; (iii) Tara Pharmacy dispenses medications including controlled substances pursuant to those invalid prescriptions; and (iv) drugs dispensed without a valid prescription are not payable under Medicare, Medicaid, and other federal health care programs. As a direct, proximate and foreseeable result of Defendants' conduct, Defendants knowingly cause false claims to be submitted to federal health care programs and make or cause false statements and records to be made that are material to such claims.

13. Plaintiff-Relators are former employees of Tara Pharmacy. The fraud set forth in this Complaint was ongoing when they joined Tara Pharmacy and continued through their departures from the Pharmacy in 2019. Relators believe and allege that the fraud continues to the present day.

14. This action seeks to recover damages and civil penalties on behalf of the United States of America arising from false and/or fraudulent statements, records, and claims made and caused to be made by Defendants and/or their agents, employees and co-conspirators, in violation of the Federal Civil False Claims Act, 31 U.S.C. §§ 3729–33, as amended ("the FCA").

15. The FCA was originally enacted during the Civil War. Congress substantially amended the Act in 1986—and, again, in 2009 and 2010—to enhance the ability of the United States government to recover losses sustained as a result of fraud against it.

16. The Act was amended in 1986 because Congress found that fraud in federal programs was pervasive and that the Act, which Congress has characterized as the primary tool for combating fraud against the federal government, was in need of modernization. Congress intended that the 1986 amendments would create incentives for individuals with knowledge of fraud against the government to disclose the information without fear of reprisals or government

inaction, and would encourage the private bar to commit legal resources to prosecuting fraud on the government's behalf.

17. Likewise, the 2009 and 2010 amendments were introduced to fill gaps in the coverage of the Act and to correct ambiguities in the drafting and misinterpretations of the intended scope of the Act that had emerged in case law in the more than 20 years that had passed since the 1986 amendments.

18. As amended in the Fraud Enforcement and Recovery Act of 2009 ("FERA"), the Act imposes liability upon any person who, *inter alia*: "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;" "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;" or "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729 (a)(1)(A)-(B), (G).

19. As amended by FERA, a "claim" is defined as "any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that – (i) is presented to an officer, employee, or agent of the United States; or (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government – (I) provides or has provided any portion of the money or property requested or demanded; or (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded." 31 U.S.C. § 3729(b)(2)(A).

20. Any person who violates the Act is liable for a civil penalty of up to $11,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990, for each violation of 31 U.S.C. § 3729, plus three times the amount of the damages sustained by the United States.

21. The Act allows any person having information about false or fraudulent claims to bring an action for herself and the United States, and to share in any recovery. The Act requires that the complaint be filed under seal for a minimum of 60 days (without service on the defendant during that time) to allow the government time to conduct its own investigation and to determine whether to join the suit.

22. Based on these provisions, Plaintiff-Relators seek to recover all available damages, civil penalties, and other relief for federal and state violations alleged herein, in every jurisdiction to which Defendants' unlawful and dangerous misconduct has extended.

II. PARTIES

23. Plaintiff-Relator Alex Sproule ("Relator Sproule" or "Mr. Sproule") is a resident of Alabama. Mr. Sproule is a pharmacist licensed in the State of Alabama and was employed by Defendant Tara Pharmacy SE, LLC at Tara Pharmacy's location in Birmingham, Alabama from approximately March 2017 until December 2019. He has a Doctor of Pharmacy degree from Samford University.

24. Plaintiff-Relator Nicholas Fuhrmann ("Relator Fuhrmann" or "Mr. Fuhrmann") is a resident of Alabama. He has been a licensed pharmacy technician since 2014 and was employed by Defendant Tara Pharmacy SE, LLC at Tara Pharmacy's location in Birmingham, Alabama from approximately July 2014 until approximately August 2019.

25. Plaintiff-Relators bring this action on behalf of the United States of America, the real party in interest.

26. Defendant Aurora Cares LLC d/b/a Tara Cares ("Tara Cares") is a privately-held company incorporated in New York. Its headquarters are in Orchard Park, New York. Tara Cares owns, manages, operates, and/or controls a large number of long-term care facilities. Tara Cares also owns, manages, and/or controls Defendant Tara Pharmacy SE, LLC.

27. Defendant Tara Pharmacy SE, LLC ("Tara Pharmacy") is a "closed door" pharmacy, meaning that it dispenses drugs only to residents of long-term care facilities that are owned, managed, operated, and controlled by Defendant Tara Cares. Tara Pharmacy does not provide retail pharmacy service. It has three locations: one in Birmingham, Alabama, a second in Jackson, Mississippi, and a third in St. Louis, Missouri.

28. Defendant Birmingham Nursing and Rehabilitation Center, LLC is a long-term care facility in Birmingham, Alabama that is operated, managed, owned, and/or controlled by Tara Cares.

29. Defendant Birmingham Nursing and Rehabilitation Center East, LLC is a long-term care facility in Birmingham, Alabama that is operated, managed, owned, and/or controlled by Tara Cares.

30. Defendant North Hill Nursing and Rehabilitation Center, LLC is a long-term care facility in Birmingham, Alabama that is operated, managed, owned, and/or controlled by Tara Cares.

31. Defendant Florence Nursing and Rehabilitation Center, LLC is a long-term care facility in Florence, Alabama that is operated, managed, owned, and/or controlled by Tara Cares.

32. Defendant Mobile Nursing and Rehabilitation Center, LLC is a long-term care facility in Mobile Alabama that is operated, managed, owned, and/or controlled by Tara Cares

33. Defendant Elba Nursing and Rehabilitation Center, LLC is a long-term care

facility in Elba, Alabama that is operated, managed, owned, and/or controlled by Tara Cares.

34. Defendant North Mobile Nursing and Rehabilitation Center, LLC is a long-term care facility in Eight Mile, Alabama that is operated, managed, owned, and/or controlled by Tara Cares.

35. Defendant Lakeland Nursing and Rehabilitation Center, LLC is a long-term care facility in Jackson, Mississippi that is operated, managed, owned, and/or controlled by Tara Cares.

36. Defendant Manhattan Nursing and Rehabilitation Center, LLC is a long-term care facility in Jackson, Mississippi that is operated, managed, owned, and/or controlled by Tara Cares.

37. Defendant Lake City Nursing and Rehabilitation Center, LLC is a long-term care facility in Lake City, Georgia that is operated, managed, owned, and/or controlled by Tara Cares.

38. Defendant Douglasville Nursing and Rehabilitation Center, LLC is a long-term care facility in Douglasville, Georgia that is operated, managed, owned, and/or controlled by Tara Cares.

39. Defendant Jonesboro Nursing and Rehabilitation Center, LLC is a long-term care facility in Jonesboro, Georgia that is operated, managed, owned, and/or controlled by Tara Cares.

40. Defendant Georgia Long Term Care and Consulting, PC, is a Georgia corporation located in Atlanta, Georgia. Georgia Long Term Care and Consulting provides physician services to nursing homes, including to Defendant Lake City Nursing and Rehabilitation Center.

III. JURISDICTION AND VENUE

41. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732, the latter of which confers jurisdiction on this Court for

actions brought under 31 U.S.C. §§ 3729 and 3730. Under 31 U.S.C. § 3730(e), there has been no statutorily relevant public disclosure of the "allegations or transactions" in this Complaint. Even if there had been any such public disclosure, Relators are original sources of the allegations herein because prior to any relevant public disclosure, they voluntarily disclosed to the government the information on which the allegations or transactions in the Complaint are based, and/or because they have knowledge that is independent of and materially adds to any publicly-disclosed allegations or transactions relevant to their claims, and voluntarily provided the information to the government before filing this action.

42. This Court has personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732(a), which authorizes nationwide service of process, and because Defendants have minimum contacts with the United States. Moreover, Defendants can be found in, reside, and/or transact or have transacted business in this District.

43. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and 1395(a) and 31 U.S.C. § 3732(a) because Defendants can be found in and/or transact or have transacted business in this District. In addition, statutory violations, as alleged in this Complaint, occurred in this District.

IV. APPLICABLE LAW

A. The Controlled Substances Act

44. The CSA regulates entities that dispense controlled substances by establishing controls over all stages of the chain of distribution of controlled substances in the United States, including practitioners and pharmacies, through a closed and monitored system which makes it unlawful to manufacture, distribute, dispense, or possess any controlled substance except as authorized by the CSA. 21 U.S.C. §§ 801 *et seq.* The Attorney General is authorized to

promulgate regulations for "the registration and control of the manufacture, distribution, and dispensing of controlled substances." 21 U.S.C. § 821.

45. Under the CSA, "controlled substances are strictly regulated to ensure a sufficient supply for legitimate medical . . . purposes and to deter diversion of controlled substances to illegal purposes. The substances are regulated because of their potential for abuse and likelihood to cause dependence when abused and because of their serious and potentially unsafe nature if not used under the proper circumstances." 75 Fed. Reg. 61,613 – 61,617 (Oct. 6, 2010) (DEA Policy Statement, "Role of Authorized Agents in Communicating Controlled Substance Prescriptions to Pharmacies").

46. Controlled Substances are organized into five schedules according to the characteristics of each substance.

47. Schedule I contains drugs with a "high potential for abuse" that have "no currently accepted medical use in treatment," and for which "[t]here is a lack of accepted safety for use of the drug . . . under medical supervision." 21 U.S.C. § 812(b)(1).

48. Schedule II contains drugs with a "high potential for abuse" that "may lead to severe psychological or physical dependence" but nonetheless have "a currently accepted medical use in treatment." 21 U.S.C. § 812 (b)(2).

49. Schedule III contains drugs for which, although the potential for abuse is lower than a Schedule II drug, such abuse may lead to moderate "physical dependence or high psychological dependence." Schedule III drugs also have a "currently accepted medical use." 21 U.S.C. § 812 (b)(3).

50. Schedule IV contains drugs that, although having a lower abuse potential than Schedule III drugs, may still lead to a physical or psychological dependence when abused. 21

U.S.C. § 812(b)(4).

51. Schedule V contains drugs that have legitimate medical uses and have the least potential for abuse. 21 U.S.C. § 812(b)(5).

52. The CSA makes it "unlawful for any person knowingly or intentionally to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance," except as specifically authorized by the CSA. 21 U.S.C. § 841(a)(1).

53. Entities that dispense controlled substances are required to have a valid DEA registration number and are referred to by DEA regulations as a "registrant." 21 C.F.R. §§ 1301.11(a) and 1300.01.

54. Under the CSA, a practitioner is a physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist or a pharmacy. 21 C.F.R. § 1300.01(b).

55. The CSA prohibits any manufacturer, distributor, or dispenser, including a pharmacy, from distributing or dispensing a controlled substance without a valid prescription. 21 U.S.C. § 829(a) and (b).

56. To be valid, a prescription for a controlled substance of any schedule shall:

(i) be dated as of, and signed on, the day when issued;

(ii) bear the full name and address of the patient;

(iii) bear the drug name, strength, dosage form, quantity prescribed, and directions for use; and

(iv) bear the name, address and registration number of the practitioner.

21 C.F.R. § 1306.05(a). The prescription must also be issued only pursuant to "a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a).

57. Each element of a valid prescription must be specified by the prescribing practitioner and cannot be delegated to an employee or other agent of the practitioner. 75 Fed. Reg. 61,613, 61,614 (Oct. 6, 2010).

58. Because of the high potential for abuse relative to other controlled substances, Schedule II drugs may be dispensed only pursuant to an original written prescription signed by the practitioner or, in an emergency situation, an oral prescription from the practitioner prior to dispensing the drug. 21 U.S.C. § 829(a); 21 C.F.R. § 1306.11(a) and (d). For purposes of long-term care facility ("LTCF") residents, a valid prescription that is transmitted via facsimile to the pharmacy serves as the original written prescription. 21 C.F.R. § 1306.11(f).

59. Additionally, prescriptions for a Schedule II controlled substance may not be refilled for a quantity of a full thirty day supply. Instead, a new prescription is required for a new thirty day supply. 21 U.S.C. § 829(a).

60. An emergency situation is one "in which the prescribing practitioner determines: (a) That immediate administration of the controlled substance is necessary, for proper treatment of the intended ultimate user; and (b) That no appropriate alternative treatment is available,

including administration of a drug which is not a controlled substance under schedule II of the Act[;] and (c) That it is not reasonably possible for the prescribing practitioner to provide a written prescription to be presented to the person dispensing the substance, prior to the dispensing." 21 C.F.R. § 290.10.

61. Under those circumstances, a pharmacist may dispense a controlled substance listed in Schedule II upon receiving an oral authorization of a prescribing practitioner, provided that:

> (i) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during only the emergency period;
>
> (ii) The pharmacist shall immediately reduce the prescription to a writing that meets the requirements of 21 C.F.R. § 1306.05, except for the signature of the prescribing individual practitioner;
>
> (iii) If the prescribing individual is not known to the pharmacist, the pharmacist must make a reasonable effort to determine that the oral authorization came from a registered individual practitioner, which may include a callback to the prescribing individual practitioner and/or other good faith efforts to ensure the identity of the prescriber;
>
> (iv) The pharmacy must receive a written prescription for the prescribing individual practitioner within seven days of the oral prescription.

21 C.F.R. § 1306.11(d).

62. LTCFs often maintain "narcotics boxes," "emergency kits," or "stat boxes" that contain small quantities of several drugs, including Schedule II drugs, that are intended to be used by the long-term care facility only in emergency situations. An LTCF not registered with

the DEA may only place such kits pursuant to state regulations or authorizations that set out safeguards for the access to and use of such kits. Drug Enforcement Administration Pharmacist's Manual, App'x H (Rev. 2010), *available at*: https://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf. Among other things, state regulations establish "[t]he emergency medical conditions under which the controlled substances may be administered . . . including the requirement that controlled substances be administered by authorized personnel only as expressly authorized by an individual practitioner and in compliance with the provisions of 21 C.F.R. §§ 1306.11 [which governs prescriptions for Schedule II drugs] and 1306.21 [which governs prescriptions for Schedule III-V drugs]." *Id.*

63. Deviation from the requirements for dispensation under "emergency medical conditions" through other orders "purporting to be a prescription" are not "prescriptions within the meaning and intent of [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." 21 C.F.R. § 1306.04(a).

64. As a result, the "responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." *Id.* Thus, a pharmacist may not fill a controlled substance prescription unless it has been issued for a legitimate medical purpose.

65. Moreover, "[a] prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice . . ." 21 C.F.R. § 1306.06. A pharmacist is required to refuse to fill a prescription if he or she knows or has reason to know that the prescription was not written for a legitimate medical purpose. *See* 21 C.F.R. §§ 1306.04,

1306.06.

B. State Controlled Substances Acts

66. The Uniform Controlled Substances Act ("Uniform CSA") was originally drafted by the United States Department of Justice in 1969 and promulgated by National Conference of Commissioners on Uniform State laws in 1970. One of the stated goals in promulgating the Uniform CSA was to foster parallel laws between the states and the federal government. The Uniform Act was updated in 1990, and again in 1994, to incorporate relevant changes made in the federal CSA.

67. Nearly every state in the United States—including the states in which Defendants operate—has adopted either the 1970, 1990 or 1994 version of the Uniform CSA. Because the Uniform CSA was modeled after federal drug laws, the provisions in the federal CSA are similar to the state controlled substance laws.

68. Every state and territory in the United States has adopted the federal practice of organizing controlled substances into schedules according to the characteristics of each substance.

69. Although the definition of a valid prescription varies slightly across jurisdictions, every state and territory in the United States prohibits the dispensing of a Schedule II controlled substance in non-emergency situations without a written hard-copy or electronic prescription issued by a licensed practitioner.

i. Alabama

70. Alabama's Uniform Controlled Substances Act is codified at Ala. Code 1975 §§ 20-2-1 *et seq.*

71. To be valid, "[a]ll prescriptions for controlled substances shall . . . be dated as of,

and signed on, the day when issued," "shall bear the drug name, strength, dosage form, and quantity prescribed," and "shall bear direction for use." Ala. Admin. Code r. 540-X-4-.06(1). *Cf.* 21 C.F.R. § 1306.05(a).

72. Although "[a] prescription may be prepared by an employee or agent of the physician for the signature of the physician," "the prescribing physician is ultimately responsible for insuring that the prescription meets the requirements of this regulation." Ala. Admin. Code r. 540-X-4-.06(4). Moreover, a physician "shall not delegate the responsibility of determining the type, dosage form, frequency of application and number of refills of the drug prescribed." Ala. Admin. Code r. 540-X-4-.06(5).

73. Alabama regulations further provide that:

(i) It is improper for any prescription for a controlled substance to be signed by any person in the place of or on behalf of the prescribing physicians.

(ii) It is improper, under any circumstances, for a physician to pre-sign blank prescription pads or forms and make them available to employees or support personnel.

(iii) It is improper for a physician to utilize blank prescription pads upon which the signature of the physician has been mechanically or photostatically reproduced.

Ala. Admin. Code r. 540-X-4-.06(7)-(9).

74. Consistent with federal law, Alabama law provides that, except in emergency situations, Schedule II drugs cannot be dispensed upon oral orders. Ala. Admin. Code r. 540-X-4-.06(2). Rather, such prescriptions must be in written form and contain the prescriber's non-electronic, handwritten signature. *Id.*

75. In emergency situations, Alabama law permits pharmacists to dispense Schedule II drugs pursuant to oral prescriptions on terms similar to federal law. *Cf.* Ala. Code § 20-2-58(g) *with* 21 C.F.R. § 1306.11(d).

76. Additionally, Schedule II drugs may not be refilled. Ala. Admin. Code r. 680-X-2-.26(1)(a)-(b).

77. "A prescription written for Schedule II substances for a resident of a long-term care facility may be transmitted . . . to the dispensing pharmacy by facsimile. The facsimile shall serve as the original written prescription." Ala. Code § 20-2-58(c).

78. Drugs in emergency kits at LTCFs can only be dispensed by authorized personnel consistent with the following requirements:

- The contents of the Emergency kit shall consist of those drugs needed to effectively manage a critical care incident or need of a patient. A copy of the list of the contents of the emergency kit shall be maintained both at the institution and the pharmacy supplying the drugs.
- All emergency kit drugs shall be provided and sealed by a pharmacist who is licensed to engage in the practice of pharmacy in this state;
- The supplying pharmacist and the medical staff of the institutional facility shall jointly determine the drugs, by identity and quantity, to be included in emergency kits;
- Emergency kits shall be stored in secured areas to prevent unauthorized access, and to ensure a proper environment for preservation of the drugs within them;
- The exterior of each emergency kit shall be labeled so as to clearly indicate that it is an emergency drug kit and that it is for use in emergencies only. The label shall

contain a listing of the Drugs contained in the kit, including name, strength, quantity, and expiration date of the contents, and the name, address(es), and telephone number(s) of the supplying pharmacist;

- Drugs shall be removed from emergency kits only pursuant to a valid order of an authorized practitioner;
- Whenever an emergency kit is opened, the supplying pharmacist shall be notified and the pharmacist shall stock and reseal the kit within a reasonable time but not more than 72 hours, so as to prevent risk of harm to patients; and
- The expiration date of an emergency kit shall be the earliest date of expiration of any drugs supplied in the kit. Upon the occurrence of the expiration date, the supplying pharmacist shall replace the expired drug.

Ala. Admin. Code 680-X-2-.18(4)(d).

ii. Georgia

79. The Georgia Controlled Substances Act is codified at Ga. Code Ann. §§ 16-13-20 *et seq.*

80. Consistent with federal law, "[a]ll controlled substance prescription drug orders issued by the authorized practitioner shall . . . be signed and dated on the same day when issued," "shall bear the name and address of the patient, the drug name, strength, dosage form, and quantity prescribed," and "directions for use." Ga. Comp. R. & Regs. 480-22-.03(a); *Cf.* 21 C.F.R. § 1306.05(a).

81. In addition, for a prescription for a controlled substance to be lawful:

> [I]t must be issued for a legitimate medical purpose by an authorized individual practitioner acting in the usual course of his or her professional

> practice. The responsibility for the proper prescribing of controlled substances is upon the prescribing practitioner, but the pharmacist is responsible for the proper filling of the prescription drug order. Any person knowingly filling a purported prescription drug order, as well as the person issuing it, shall be subject to disciplinary action.

Ga. Comp. R. & Regs. 480-22-.02(1); *see also* Ga. Code Ann. § 16-13-41(f).

82. It is "unlawful for any practitioner to issue any prescription document signed in blank." Ga. Code Ann. § 16-13-41(h).

83. Prescriptions for Schedule II drugs be in writing, except in emergency situations. Ga. Code Ann. § 16-13-41(a), (c); Ga. Comp. R. & Regs. 480-22-.04.

84. In an emergency situation where a Schedule II drugs is needed but a written prescription cannot be obtained, an oral authorization from the prescribing practitioner is permissible under the same criteria as outlined in 21 C.F.R. § 1306.11(d), including that requirement that the pharmacist make reasonable efforts to determine that the oral authorization came from the prescribing practitioner when the pharmacist does not know the identity of the prescribing practitioner. Ga. Comp. R. & Regs. 480-22-.04.

85. Schedule II drugs may not be refilled. Ga. Code Ann. § 16-13-41(c); Ga. Comp. R. & Regs. 480-22-.05.

86. For purposes of long-term care facility residents, a valid prescription for a Schedule II drug that is transmitted via facsimile to the pharmacy serves as the original written prescription. Ga. Comp. R. & Regs. 480-22-.04(5).

iii. Mississippi

87. The Mississippi Uniform Controlled Substances Law is codified at Miss. Code.

Ann. §§ 41-29-101, *et seq.*

88. "All prescriptions for controlled substances must be written in strict compliance with [the Mississippi Uniform Controlled Substances Law] and [21 C.F.R. Pt. 1306—Prescriptions]. 30 Code Miss. R. Pt. 2640, R. 1.10(A).

89. To be valid, a prescription for a controlled substance must, among other requirements, be "issued [by a practitioner] for a legitimate medical purpose in the usual course of professional practice." Miss. Code. Ann. § 41-29-137(f)(1).

90. Consistent with the requirement that prescriptions be issued only in the usual course of professional practice, prescribers "must not permit any prescription for controlled substances to be signed by anyone in [their] place or on [their] behalf . . ." 30 Code Miss. R. Pt. 2640, R. 1.10(D).

91. Mississippi law also prohibits the use of pre-signed prescription pads and order forms. 30 Code Miss. R. Pt. 2640, R. 1.10(E).

92. Consistent with federal law, Mississippi requires that Schedule II drugs be dispensed only upon a "written valid prescription of a practitioner," except in emergency situations. Miss. Code. Ann. § 41-29-137(a). To be valid, "[t]he prescription must bear an original signature of the prescriber," and, if transmitted electronically, "must comply with DEA regulations." 30 Code Miss. R. Pt. 3001, Art. XVII.

93. In an emergency situation where a Schedule II drugs is needed but a written prescription cannot be obtained, an oral authorization from the prescribing practitioner to the pharmacist is permissible provided that, among other things, the pharmacist reduces the oral prescription to writing and obtains a written prescription from the prescriber within seven days. 30 Code Miss. R. Pt. 3001, Art. XIX(1)(A).

94. Schedule II drugs may not be refilled. They require a renewed prescription issued by a licensed medical doctor. Miss. Code. Ann. § 41-29-137(a)(2); 30 Code Miss. R. Pt. 3001, Art. XIX(2).

95. For purposes of long-term care facility residents, a valid prescription for a Schedule II drug may be transmitted "directly from the prescribing practitioner to a pharmacy by facsimile," in which case the facsimile serves as the original written prescription. 30 Code Miss. R. Pt. 3001, Art. XIX.

C. Federal and State-Funded Health Care Programs

96. The federal government reimburses prescription drugs under several health care programs, including, but not limited to, Medicare, Medicaid, CHAMPUS/TRICARE, CHAMPVA, the Federal Employees Health Benefit Program, federal workers' compensation programs, and comparable state programs. A significant portion of prescriptions dispensed by Tara Pharmacy are reimbursed by one or more of these programs.

97. Federal and state-funded health care programs only reimburse prescription drugs if the drugs are dispensed upon a valid prescription.

i. Medicare

98. Medicare is federally-funded health insurance program which provides for certain medical expenses for persons who are over 65, who are disabled, or who suffer from End Stage Renal Disease.

99. The program is administered through the Department of Health and Human Services, Centers for Medicare and Medicaid Services ("CMS").

100. The Medicare Program has four parts: Part A, Part B, Part C and Part D. Medicare Part A, the Basic Plan of Hospital Insurance, covers the cost of inpatient hospital

services and post-hospital nursing facility care. Medicare Part B, the Voluntary Supplemental Insurance Plan, covers the cost of services performed by physicians and certain other health care providers, both inpatient and outpatient, if the services are medically necessary and directly and personally provided by the provider. Medicare Part C covers certain managed care plans, and Medicare Part D provides subsidized prescription drug coverage for Medicare beneficiaries.

101. The Medicare Prescription Drug Improvement and Modernization Act of 2003 added prescription drug benefits to the Medicare program under Part D. Since January 2006, the Medicare Program has provided subsidized drug coverage for all beneficiaries who elect to receive Part D benefits.

102. Part D coverage is not provided within the traditional Medicare program. Medicare Part D is based on a private market model. Medicare contracts with private entities called Part D Plan "Sponsors" to administer prescription drug plans. Part D sponsors, in turn, subcontract with pharmacies to provide drugs to Medicare Part D beneficiaries enrolled in their plans.

103. Coverage under Medicare Part D is limited to "covered Part D drugs," which are defined in part as "a drug that may be dispensed only upon a prescription." 42 U.S.C. § 1395w-102(e)(1)(A); 42 C.F.R. § 423.100. "A Part D sponsor may only provide benefits for Part D drugs that require a prescription if those drugs are dispensed upon a valid prescription." 42 C.F.R. § 423.104(h). A "valid" prescription is "a prescription that complies with all applicable State law requirements constituting a valid prescription." 42 C.F.R. § 423.100.

104. CMS provides Part D sponsors with advance monthly payments to administer the Part D benefit. The advance subsidies include the "direct subsidy," which reflects the plan's estimated cost of administering the Part D benefit, and the "low-income subsidy," which funds

subsidies that cover most or all of the out-of-pocket costs for qualifying, low-income Medicare beneficiaries.

105. Generally, when a pharmacy dispenses a drug to a Medicare beneficiary enrolled in a Part D plan, the pharmacy will submit a claim electronically on the beneficiary's behalf to the Part D sponsor (usually through the sponsor's PBM), seeking coverage for the drug. The claim submission includes all information necessary for the Part D sponsor to determine coverage, including the Medicare beneficiary's name and Medicare ID, the prescriber, the date the prescription was written, how the prescription was transmitted to the pharmacy (i.e., whether the prescription was transmitted as an electronic prescription, by phone, by fax, or as a written paper copy), the drug and quantity dispensed, the cost of the drug, the number of refills authorized, and the number of times the prescription has been filled.

106. The Part D sponsor "adjudicates" the prescription drug claim and, if it covers the claim, will pay the pharmacy based on the Part D plan's benefit design. In many cases, the plan will reimburse a portion of the total cost of the drug, leaving the pharmacy to collect the balance from the patient as a copay or coinsurance.

107. Part D sponsors must document and report to CMS information on the cost of each drug transaction they cover. Sponsors submit a Prescription Drug Event ("PDE") record electronically for each prescription that is filled for an enrolled plan member. A PDE record is an electronic record comprising numerous fields with detailed information about each drug transaction. Collectively, the PDE records a Part D sponsor submits to CMS will report the sponsor's prescription drug costs under the plan.

108. The PDE records the sponsor submits determine CMS's payments to the Part D plan. If a sponsor's actual costs exceed its estimated costs by more than 5 percent, CMS will pay

the sponsor an additional amount known as a "risk sharing" payment. If the sponsor's actual costs are more than 5 percent below its estimated costs, the sponsor must make a "risk sharing" payment to CMS.

109. As a condition for receiving a monthly payment from CMS, a Part D sponsor must certify the accuracy, completeness and truthfulness of all data related to payment. Data related to payment may include enrollment information, claims data, bid submission data and any other data specified by CMS. 42 C.F.R. § 423.505(k)(l). If the claims data, which include PDE records, have been generated by a related entity, contractor, or subcontractor of a Part D plan sponsor, that entity, contractor or subcontractor must similarly certify that the claims data it has generated are accurate, complete and truthful and must acknowledge that the claims data will be used for the purposes of obtaining federal reimbursement. 42 C.F.R. § 423.505(k)(3).

110. CMS regulations require that all subcontracts between Part D plan sponsors and downstream entities, including pharmacies and PBMs contain language obligating the pharmacy to comply with all applicable federal laws, regulations, and CMS instructions. 42 C. F.R. § 423.505(i)(4)(iv).

ii. Medicaid

111. Medicaid is a public assistance program providing for payment of medical expenses for certain groups, primarily the poor and disabled. Funding for Medicaid is shared between the federal government and state governments.

112. Although Medicaid is administered on a state-by-state basis, the state programs adhere to federal guidelines. Federal statutes and regulations restrict the drugs and drug uses that the federal government will pay for through its funding of state Medicaid programs.

113. Federal reimbursement for prescription drugs under the Medicaid program is

limited to "covered outpatient drugs." 42 U.S.C. §§ 1396b(i)(10), 1396r-8(k)(2), (3). Such drugs "may be dispensed only upon a prescription." 42 C.F.R. § 447.502. Drugs dispensed upon invalid prescriptions do not qualify for reimbursement. *See id.*; *see also* 42 U.S.C. § 1396d(a)(12).

iii. Other Federal Health Care Programs

114. In addition to Medicaid and Medicare, the federal government reimburses a portion of the cost of prescription drugs under several other federal health care programs, including but not limited to TRICARE, CHAMPVA, the Federal Employees Health Benefit Program, and federal workers' compensation programs.

115. TRICARE, administered by the United States Department of Defense, is a federally-funded program that provides medical benefits to certain relatives of active duty, deceased, and retired service members or reservists, as well as to retirees.

116. CHAMPVA, administered by the United States Department of Veterans Affairs, is a health care program for the families of veterans with 100 percent service-connected disability.

117. The Federal Employee Health Benefit Program, administered by the United States Office of Personnel Management, provides health insurance for federal employees, retirees, and survivors.

118. These federal programs reimburse prescription drugs on terms similar to Medicare and Medicaid, meaning that the drugs may only be reimbursed when they are dispensed pursuant to a valid prescription. *See, e.g.*, 32 C.F.R. § 199.4(d)(1) and (d)(3)(vi) (TRICARE only covers prescription drugs when prescribed by a physician or other authorized provider "in accordance with good medical practice and standards of quality"); 38 C.F.R. §§ 17.272(a)(12) (CHAMPVA

benefits only cover "medical services and supplies that are medically necessary and appropriate" and exclude from coverage "[s]ervices and supplies not provided in accordance with accepted professional medical standards . . . .").

V. ALLEGATIONS

A. Tara Pharmacy Dispenses Drugs Without Valid Prescriptions.

119. Tara Pharmacy regularly dispenses drugs, including controlled substances, without valid prescriptions to residents of LTCFs that Tara Cares owns, operates, and controls.

120. A significant number of Tara LTCF residents are beneficiaries of Medicare, Medicaid, and other federal health care programs.

121. The fraudulent prescription orders come from LTCFs that Tara Cares owns, operates, manages, services, and/or controls in Alabama, Mississippi, and Georgia. Those LTCFs include, but are not limited to, Florence Nursing and Rehabilitation Center, LLC in Florence, Alabama; Birmingham Nursing and Rehabilitation Center East, LLC in Birmingham, Alabama; Lakeland Nursing and Rehabilitation Center, LLC in Jackson, Mississippi; Manhattan Nursing and Rehabilitation Center, LLC in Jackson, Mississippi; Lake City Nursing and Rehabilitation Center, LLC in Lake City, Georgia; Douglasville Nursing and Rehabilitation Center, LLC in Douglasville, Georgia; and Jonesboro Nursing and Rehabilitation Center, LLC in Jonesboro, Georgia.

122. Many of the invalid prescriptions are for Schedule II drugs, such as oxycodone, fentanyl, and morphine, which can cause significant harm and have a high potential for abuse. Other invalid prescriptions are for non-Schedule II drugs, such as Clonazepam (Schedule IV), Tramadol (Schedule IV), and Lorazepam (Schedule IV), which also can cause significant harm and are prone to abuse. In other cases, the invalid prescriptions are for non-controlled

substances—such as Depakote, Haldol, Desreyl, Seroquel, Desryel, Namenda and Aricept—which can have dangerous side effects and need to be closely monitored by physicians. This is particularly true for elderly patients, who are commonly on multiple drugs at the same time and thus face increased risks of side effects and adverse drug interactions.

123. Tara LTCFs send orders for controlled substances to Tara Pharmacy through two main channels. The first and most common channel that Tara LTCFs use to transmit orders for controlled substances is by fax. Second, staff at Tara LTCFs also seek to transmit prescriptions through oral telephone orders.

124. Tara Pharmacy receives all orders through a system called DocuTrack, which assigns each order a unique number. Orders received for controlled substances require that the pharmacy generate a request form for a prescription to the physician that is sent by fax. No request form is generated for non-controlled substances.

125. Tara Pharmacy then transcribes orders received through DocuTrack into a prescription billing and data software system called QS/1 for processing and billing. Orders coming from nursing home for both controlled and non-controlled substances are processed through QS1.

126. Prescriptions are then dispensed by Tara Pharmacy, which packages the drugs and sends them to Tara LTCFs through a third party courier.

127. The orders that Tara Pharmacy receives from the Tara LTCFs for prescription drugs, including Schedule II narcotics, frequently lack an original signature from the prescribing physician or other authorized prescriber and therefore are not valid prescriptions. Although a pharmacy contracted with an LTCF may properly receive prescriptions by fax, the facsimile copy of a prescription is not valid unless the original prescription contains an original signature

from the prescribing practitioner. The orders that Tara Pharmacy receives by fax do not reflect original signatures. Instead, most orders contain auto-stamped or photocopies of provider signatures. Those copies are often suspect, with Tara Pharmacy receiving multiple orders in a large batch, each bearing an identical signature, or orders in which a provider's photocopied signature appears different from the provider's signature on previous orders. In each case, the prescription is invalid because it does not contain an original signature from an authorized provider.

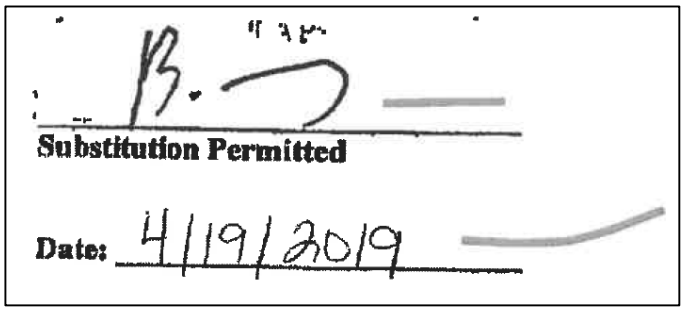
128. The following are examples of an ongoing pattern and practice of invalid prescriptions that Tara Pharmacy has filled on behalf of residents of Tara LTCFs, resulting in false or fraudulent claims.

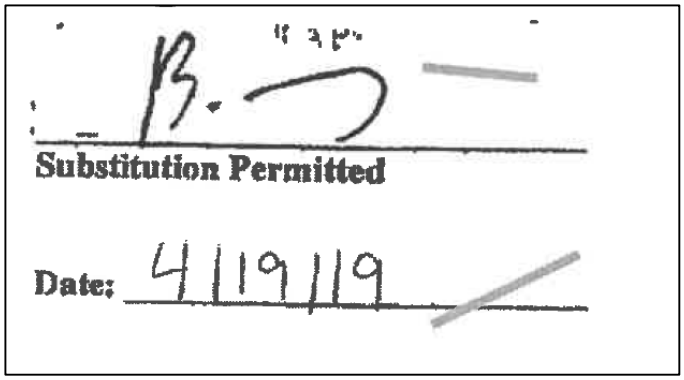
129. Tara Pharmacy regularly receives orders from Tara LTCFs in bulk, with each order displaying an identical, duplicated copy of a signature from an authorized practitioner, instead of an original signature from that practitioner. For example, on April 19, 2019, Tara Pharmacy received multiple faxed prescription orders from Florence Nursing and Rehabilitation Center that contained duplicate, copied signatures of Dr. Bardya Naeini. These faxed documents were not valid prescriptions because they did not reflect original practitioner signatures. Nonetheless, Tara Pharmacy filled the orders and did not seek original signatures from the practitioners for those orders. The faxed orders include the following:

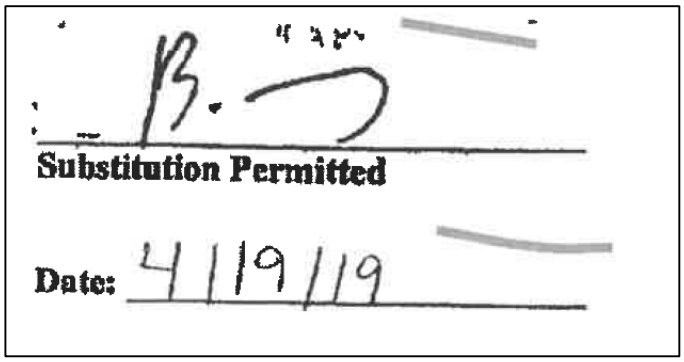
- An order for 30 Tramadol HCL 50mg tablets (a Schedule IV drug) for patient E.G.;
- An order for 45 Norco 5/325mg tablets (a Schedule II drug) for patient S.H.;
- An order for 90 Norco 7.5/325mg tablets for patient R.K;
- An order for 60 Norco 7.5mg tablets for patient S.Ha.;
- An order for 60 Oxycodone 10mg tablets (a Schedule II drug) for patient R.R.;

- An order for 60 Norco 5/325mg tablets for patient J.H.;
- An order for 120 tablets of Oxycodone IR 5mg tablets for patient S.G. and a second order of 120 Tramadol 50mg tablets for the same patient;
- An order for 90 Norco 10/325mg tablets for patient B.K.;
- An order for 180 Norco 5/325mg tablets for patient W.B.;
- An order for 120 Percocet 7.5/325mg tablets (a Schedule II drug) for patient D.W. and a second order for 30 Lyrica 75mg capsules (a Schedule V drug) for the same patient;
- An order for 180 tablets of Norco 10/325mg tablets for patient W.V.;
- An order for 60 Clonazepam 0.5mg tablets (a Schedule IV drug) for patient V.R., and the second for 180 Oxycodone/Acetaminophen 10/325mg tablets (a Schedule II drug) for the same patient;
- An order for 180 Norco 10/325mg tablets for patient R.T.; and
- An order for 12 Lorazepam 1mg tablets (a Schedule IV drug) for patient R.A.

As representative examples, the following are identical signatures on the orders for patients E.G., S.H., and R.K.:





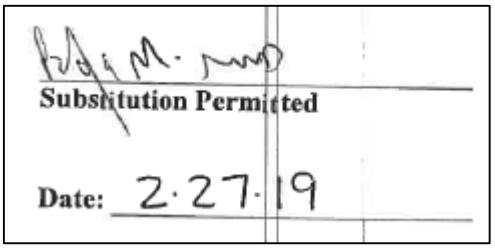


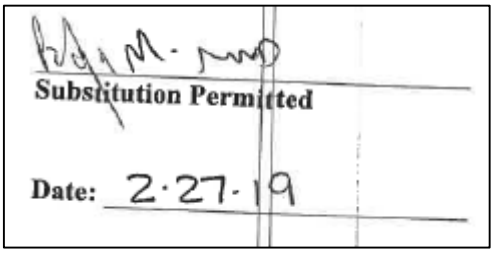
130. Between February 20, 2019 and February 27, 2019, Tara Pharmacy received and filled at least 16 prescription orders from Florence Nursing and Rehabilitation purportedly written by Dr. Naeini with an apparently photocopied signature that was different from the signature on the prescriptions purportedly written by Dr. Naeini on April 19, 2019. These orders were not valid prescriptions because they did not contain valid practitioner signatures. The orders included the following:

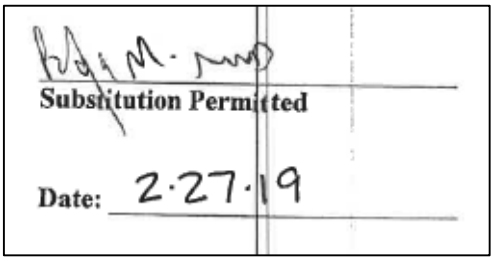
- A February 27th order for 60 Norco 10/325mg tablets for patient J.G.;
- A February 27th order for 30 Norco 5/325mg tablets for patient B.S.;
- A February 27th order for 90 Norco 10/325mg tablets for patient L.G.;
- A February 27th order for 60 Ativan 0.5mg tablets (a Schedule IV drug) for patient L.Gi.;
- A February 27th order for 60 Norco 5/325mg tablets for patient J.P.;

- A February 27th order for 30 Diazepam 5mg tablets (a Schedule IV drug) for patient B.C. and a second order on the same date for 60 Norco 7.5mg tablets for the same patient;
- A February 27th order for 10 Fentanyl 25mcg patches (a Schedule II drug) for patient B.G.;
- A February 27th order for 60 Norco 7.5/325mg tablets for patient B.Ga.;
- A February 27th order for 30 Norco 5/325mg tablets for patient D.B.;
- A February 26th order for 30 Methadone HCL 5mg tablets (a Schedule II drug) for patient R.L.; and
- A February 26th order for 30 Methadone HCL 5mg tablets for Patient B.B.

As representative examples, the following are identical signatures on the orders for patients J.G. and B.S.:



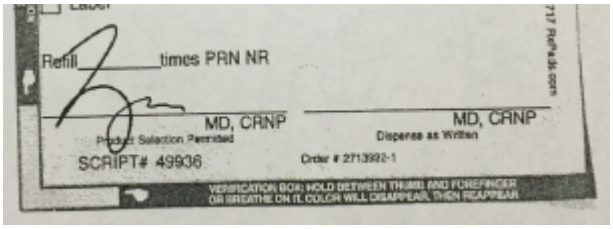


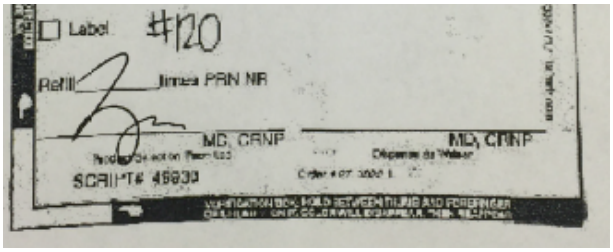


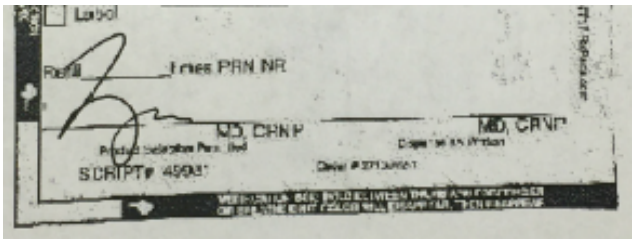
Relators are aware of dozens of other examples where Tara Pharmacy dispensed drugs pursuant to orders containing copies of Dr. Naeini's signature.

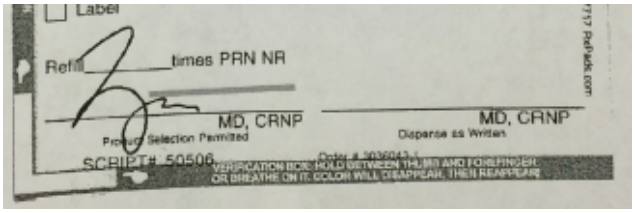
131. Tara Pharmacy has also received and filled orders containing invalid prescriber signatures for residents of Birmingham Nursing and Rehabilitation Center East, including orders with auto-stamped copies of Dr. Lee Wimberly's signature that appear to come from her office. For example, on December 13, 2019, Tara received four orders containing auto-stamped signatures of Dr. Wimberly:

- An order for 60 Norco 10/325mg tablets for patient M.R.;
- An order for 120 Norco 7.5/325mg tablets for patient Sh.Ha.;
- An order for 30 Norco 10/325mg tablets for patient M.W.; and
- An order for 120 800mg Neurontin tablets for patient D.L.









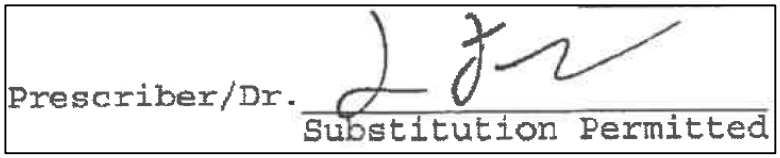
These orders were not valid because they did not contain valid prescriber signatures.

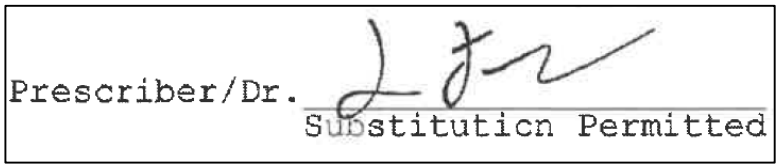
132. Tara Pharmacy also dispenses drugs pursuant to invalid written prescriptions for residents of Manhattan Nursing and Rehabilitation Center and Lakeland Nursing and Rehabilitation Center, both in Jackson, Mississippi. For example, between May 12, 2017 and May 19, 2017, Tara Pharmacy received and filled eight orders for controlled substances containing what appear to be auto-stamped duplicate signatures of Dr. Todd Fulcher for eight Medicare beneficiaries residing in the Manhattan and Lakeland LTCFs:

- A May 12th order for 60 Norco 7.5/325mg tablets (a Schedule II drugs) for patient B.D.;
- A May 15th order for 120 Norco 10/325mg tablets (a Schedule II drug) for patient A.C.;
- A May 16th order for 30 Ambien 5mg tablets (a Schedule IV drug) for patient M.D.;
- A May 17th order for 10 tablets of Fentanyl 100mcg patches (a Schedule II drug) for patient L.M.;
- A May 18th order for 60 Norco 10/325mg tablets (a Schedule II drug) for patient B.H.;
- A May 18th order for 30 OxyContin 10mg tablets (a Schedule II drug) for patient J.W.;
- A May 19th order for 10 Fentanyl 25mcg patches (a Schedule II drug) for patient P.S.;

- A May 19th order for 90 Oxycodone HCL 5mg tablets (a Schedule II drug) for patient A.H.

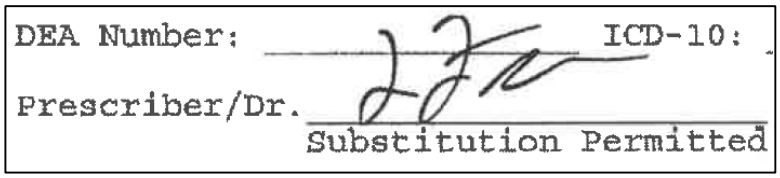
As representative examples, the following are the signatures on the prescriptions for patients B.D., A.C., and M.D., each bearing a separate date:

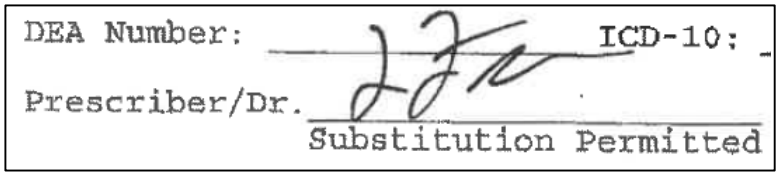




These orders were not valid prescriptions because they did not contain valid practitioner signatures.

133. Similarly, on July 24, 2019, Tara Pharmacy received and filled two orders for residents of the same LTCFs who are Medicare beneficiaries that also appear to have auto-stamped, duplicate signatures of Dr. Todd Fulcher. One order was for 60 tablets of Oxycodone HCL 5mg tablets for patient A.H. (the same patient listed in the prior paragraph). The second order was for 10 Fentanyl 25mcg patches for patient J.K. Though Tara Pharmacy's prescription form was in hard copy, both prescriptions appear to have been filled out electronically and the signatures affixed to them were duplicates:





These orders were not valid prescriptions because they did not contain original practitioner signatures.

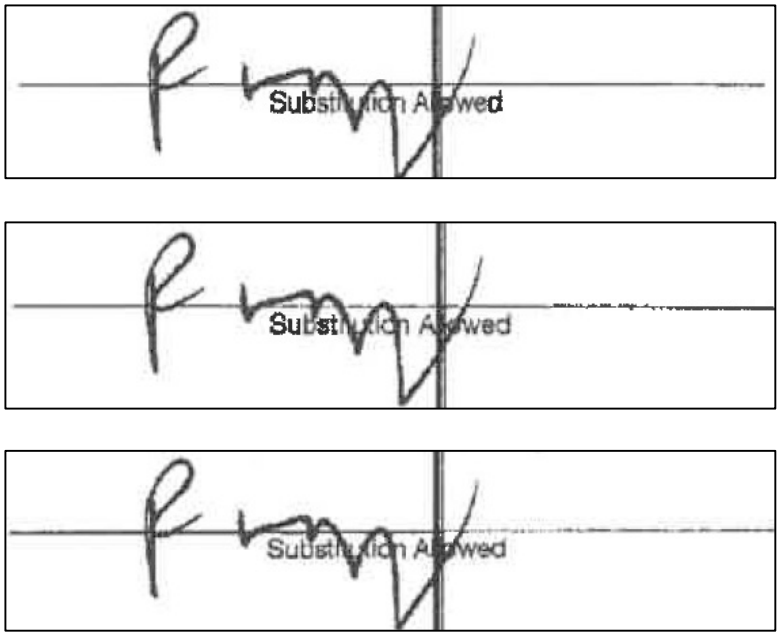
134. Tara Pharmacy also receives and fills invalid prescriptions from Tara LTCFs located in Georgia, including Lake City Nursing and Rehabilitation Center, Douglasville Nursing and Rehabilitation Center, and Jonesboro Nursing and Rehabilitation Center.

135. For example, Tara Pharmacy has received written prescriptions from Lake City Nursing and Rehabilitation that contained duplicate signatures of at least two physicians, Dr. Richard Wright and Dr. Andrew Frinks, but filled the prescriptions even though they did not contain valid practitioner signatures.

136. Orders from Lake City with duplicate signatures of Dr. Wright include the following orders dated July 24, 2019:

- 90 Oxycodone/Acetaminophen 10/325mg tablets for patient S.S. The order also indicated the prescription could be refilled twice, even though refills of Schedule II drugs are not permitted under the CSA;
- 90 Oxycodone HCL 5mg tablets for patient L.C. with two refills;
- 90 Clonazepam 0.5mg tablets for patient L.H.;
- 90 Alprazolam 0.25mg tables (a Schedule IV drug) for patient G.B.;
- 90 Tramadol HCL 50mg tablets for patient J.D.;

As representative examples, the following are signatures on the orders for patients S.S., L.H., and G.B., respectively. Each is identical to the other:



In addition to being invalid because the orders did not have valid practitioner signatures, the orders for patients S.S. and L.C. were also invalid because they permitted refills on Schedule II drugs, in violation of the CSA.

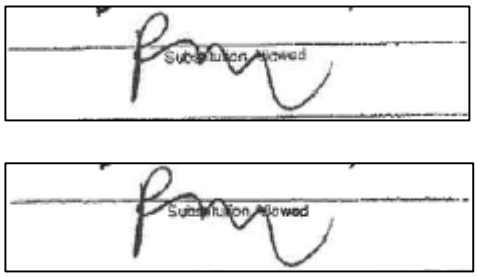
137. Tara Pharmacy also received other invalid prescriptions from Lake City with duplicate signatures of Dr. Wright, including the following:

- A June 24, 2019 order 60 Morphine Sulfate ER 30mg tablets (a Schedule II drug) for patient F.L. with three refills and a separate June 20, 2019 order for the same duplicating the June 24th order;
- An April 16, 2019 order for 30 Xanax 0.5mg tablets (a Schedule IV drug) for patient B.M.;
- An April 16, 2019 order for Zolpidem Tartrate 10mg tablets (a Schedule IV drug) for patient H.S.;
- A February 9, 2019 order for 30 Lyrica 100mg capsules for patient P.B.;
- A February 9, 2019 order for a 30-day supply of Hydrocodone/Acetaminophen

5/325mg tablets (a Schedule II drug) for patient E.F.;

- A May 24, 2018 order for 30 Clonazepam 0.5mg tablets for patient D.C.;
- A May 24, 2018 order for 30 Phenobarbital 97.2 tablets (a Schedule IV drug) for patient B.V.

As representative examples, the following are identical signatures on the orders for patients B.M. and H.S.:



In addition to being invalid because the orders did not have valid practitioner signatures, the orders for patients F.L. and I.J. were also invalid because they permitted refills on Schedule II drugs, in violation of the CSA.

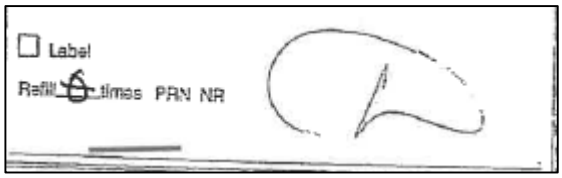
138. Tara Pharmacy has also received and filled hundreds of orders for Lake City residents with duplicate signatures of Dr. Frinks, which appear that they may originate from his office. The prescriptions were sent by Defendant Georgia Long Term Care and Consulting. Those orders include the following:

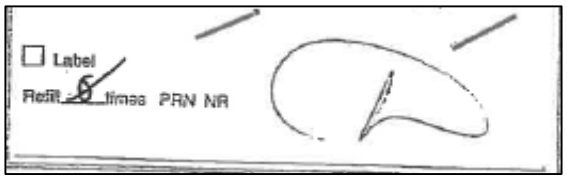
- A September 7, 2016 order for 90 tablets of Tramadol HCI 50mg for patient S.D.;
- An August 29, 2016 order 180 Ativan 1mg tablets for patient R.S.;
- An August 29, 2016 order for 1 Oxycodone 10/325mg tablet (from an emergency kit) for patient B.M.;
- An August 26, 2016 order for 60 Percocet 7.5/325mg tablets for patient E.G., a June 20, 2016 order for 120 Percocet 7.5/325mg tablets for E.G., and a July 28, 2016

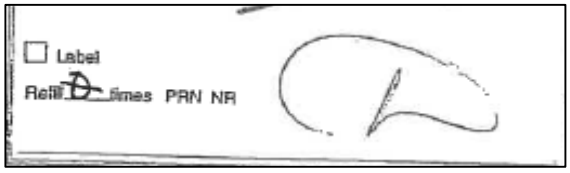
order for 90 Alprazolam 1mg tablets for E.G.;

- An August 17, 2016 order 60 Lorazepam 1mg tablets for patient A.H.; and
- A June 27, 2016 order for 60 Morphine Sulfite ER 15mg tablets for patient F.L. (that same patient received the same drug through invalid prescriptions from Dr. Wright, as described in the paragraph above).

As representative examples, the following are signatures on the orders for patients S.D., R.S., and B.M., respectively. Each is identical to the other:







These orders were not valid prescriptions because they did not contain valid practitioner signatures.

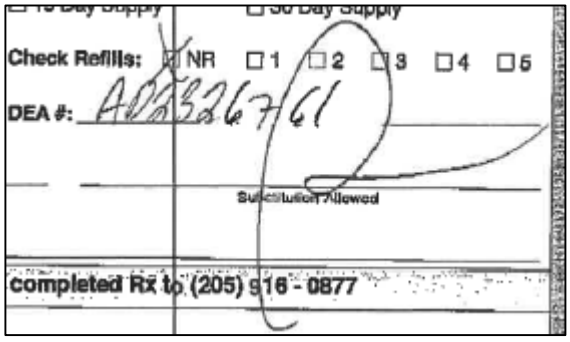
139. Tara Pharmacy has also received prescriptions from Douglasville Nursing and Rehabilitation Center and that contained duplicate signatures of multiple physicians, including Dr. Saurabh Desai, Dr. Sharon Tuckett, and Dr. Thomas Varughese, but filled the prescriptions even though they did not contain valid practitioner signatures. The following are a few examples of those orders, which Tara Pharmacy filled:

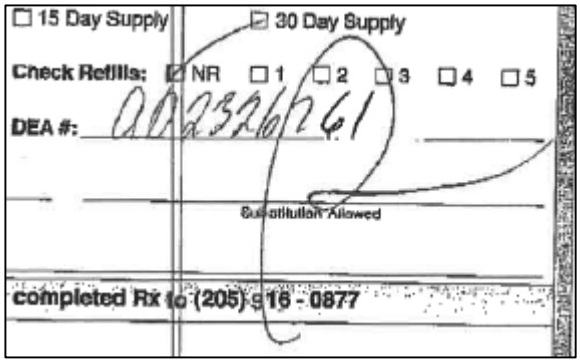
- A January 22, 2018 order for 180 Percocet 10/325mg tablets for patient D.Wo. (Dr.

Desai);

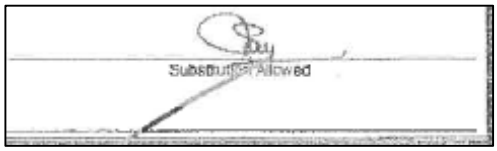
- A January 22, 2018 order for 60 Oxycodone 30mg tablets for patient J.Hi (Dr. Desai);
- A January 18, 2018 order for 60 Clonazepam 0.25mg tablets for patient M.C. (Dr. Desai);
- A January 16, 2018 order for 60 tablets of Morphine Sulfate ER 30mg tablets for patient P.Su. (Dr. Desai);
- A January 28, 2018 order for 90 Norco 5/235mg tablets for patient J.R. (Dr. Tuckett);
- An October 17, 2018 order for 3 doses of Xanax 0.5mg tablets for patient D.H. (Dr. Varughese); and
- An October 22, 2018 order for 60 Percocet 7.5/325mg tablets for patient D.H. (Dr. Varughese).

As representative examples, the following are purported signatures of Dr. Desai for patients D.Wo. and J.Hi. They are identical to each other:

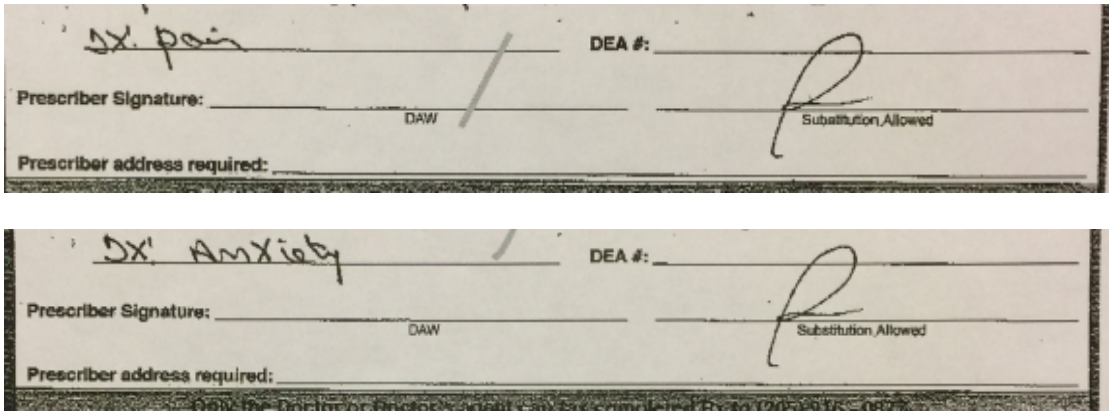




As representative examples, the following are the purported signatures of Dr. Varughese for the orders for patient D.H. They are identical to each other:



140. In some instances, Tara LTCFs fax orders with copied practitioner signatures during overnight hours when it is unlikely that the prescriber is at the facility or available to sign written orders. When Relator Sproule inquired to nurses at the LTCFs about the signatures, he was told that nurses rarely see physicians at the LTCFs and that they do what they have to do to obtain the medications. For example, at 10:35pm Central Time on February 26, 2019, Tara Pharmacy received two faxed orders for Douglasville Nursing and Rehabilitation Center patient E.M. that contained duplicate signatures of Dr. Desai. The first prescription was for 90 tablets of Tylenol with Codeine (a Schedule III drug) and the second was for 60 tablets of Lorazepam 0.5mg:



141. In other cases, Tara Pharmacy received orders overnight with prescriber signatures that may not have been copied, but that were otherwise suspect. For example, between 1:26am and 1:27am Eastern Time on October 31, 2019, Jonesboro Nursing and Rehabilitation Center sent multiple orders for patient A.G. to Tara Pharmacy in a single fax. The first order was a record of a telephone order supposedly given by Dr. Paul Harvey for 1mg tablets of Clonazepam. A licensed practical nurse entered the record at 1:16am. Ten minutes later, Jonesboro submitted a written order for a 30-day supply of the Clonazepam 1mg tablets bearing the signature of a different physician, Dr. Richard Wright. At the same time, Jonesboro submitted written orders for a 30-day supply of Morphine Sulfate ER 30mg and for a 30-day supply of Fentanyl 100mcg/hr patches, both for the same patient and bearing signatures of Dr. Wright. Although the signatures of Dr. Wright were not identical, the orders are suspicious for several reasons. First, Relators understand that it is unlikely that physicians are present in nursing homes or available to sign prescriptions during overnight hours. Second, the handwriting and ink containing the patient's name, room number, and drug information in the written orders are different from the handwriting and ink in the prescriber's signature and DEA number, indicating that a nurse or other LTCF staff member, rather than the prescriber, filled out the patient and drug information. Third, in Relators' experience, it would be unusual for one

physician to give a verbal order only to have a different physician sign a written order for the same drug within 20 minutes. For these reasons, Relators were concerned that Dr. Wright had pre-signed prescriptions like blank checks and allowed nurses to attempt to fill them. Ultimately, Tara Pharmacy did not fill these orders because they did not contain a date, but they are evidence of Defendants' pattern and practice of submitting invalid prescriptions for controlled substances.

142. Likewise, on November 1, 2019, Tara Pharmacy received a written order from Lake City at 11:43pm Central Time for patient A.P. The order was simply for "Hydrocodone" and did not indicate the quantity, strength, or directions for use. In addition, the handwriting and ink containing the patient's name, the date of the order, and the drug name were different from the handwriting and ink containing Dr. Wright's signature and DEA number. This order similarly made Relator Sproule concerned that Dr. Wright had left pre-signed prescriptions orders for nurses to attempt to fill.

143. Defendants knew that the prescriptions submitted to Tara Pharmacy were invalid and not eligible for reimbursement under federal health care programs.

144. Relator Sproule was a Pharmacist at Tara Pharmacy's Birmingham location and worked the overnight shift. Mr. Sproule saw numerous instances of purported orders for controlled substances that contained copies of physicians' signatures, rather than original signatures. Mr. Sproule also observed that there would be physician signatures on prescriptions lacking information about quantity, strength or directions for use. This made him concerned that the physicians signed prescriptions like blank checks and allowed the nurses to fill in the orders. Mr. Sproule also observed many instances where non-practitioners, such as nurses, sought to obtain oral prescriptions for controlled substances.

145. Relator Sproule did not fill orders when he doubted their legitimacy, but instead

generally sent a request to the physician to obtain a valid prescription. In some cases, the pharmacy did not obtain a response from the physician and a medicine was not dispensed. But Relator Sproule was an outlier at Tara Pharmacy. Based on documents Mr. Sproule saw through Tara Pharmacy's DocuTrack and QS/1 systems, as well as interactions with other Tara Pharmacy staff and pharmacists, he learned that other pharmacists at Tara Pharmacy routinely dispensed controlled substances pursuant to copied or otherwise invalid practitioner signatures.

146. For example, in or around April 2019, Mr. Sproule reviewed orders that Tara received from Florence Nursing and Rehabilitation Center the prior evening and noticed that they contained duplicate signatures. Mr. Sproule pulled those prescriptions aside so that they would not be dispensed and informed the pharmacist on the following shift of the invalid prescriptions. Nonetheless, when Mr. Sproule returned to work the following day, he observed that the invalid prescriptions had been approved by the pharmacist who relieved Mr. Sproule and had been shipped to Florence.

147. Relator Sproule expressed his concerns about copied practitioner signatures to his immediate supervisor, J.J. Koch, in a 2018 email that was forwarded to Tara Cares' Vice President of Pharmacy (who works in St. Louis), Keith Wallis, who in turn relayed it to the Tara Cares then-Vice President for Georgia and Alabama, Tony Wehunt and to the Director(s) of Nursing for Jonesboro and/or Lake City. Despite Relator Sproule's complaints, the conduct alleged herein continued and was ongoing at the time he resigned from Tara Pharmacy.

148. Relator Fuhrmann was a Pharmacy Technician at Tara Pharmacy's Birmingham location. Like Relator Sproule, he also generally worked the overnight shift, although he also interacted with pharmacists during other shifts. Relator Fuhrmann observed the same concerning practices as Relator Sproule, including purported orders for controlled substances for Tara LTCF

patients containing copies of physician signatures and purported orders from non-practitioners seeking to obtain oral prescriptions for controlled substances. Relator Fuhrmann relayed his concerns about the invalid prescriptions to Tara pharmacists. With the exception of Relator Sproule and one other pharmacist, pharmacists generally told Mr. Fuhrman that they would fill the orders because they could not prove the signatures had been copied because they were received by fax and no original was available for comparison.

149. In some instances, LTCF staff admitted that they had submitted invalid orders that contained copies of physician signatures. For example, on or around September 20, 2018, Tara Pharmacy received several orders for residents of Lake City. When questioned by Mr. Sproule about the validity of the practitioner's signatures on those orders, the LTCF nurse who submitted the orders conceded that the practitioner's signature had been copied.

150. On information and belief, Tara Pharmacy's practice of dispensing drugs pursuant to invalid prescriptions may have extended to other Tara LTCFs that the Pharmacy served. Those facilities include North Hill Nursing and Rehabilitation Center, LLC in Birmingham, Alabama, Birmingham Nursing and Rehabilitation Center, LLC in Birmingham, Alabama, Elba Nursing and Rehabilitation Center, LLC in Elba, Alabama, Mobile Nursing and Rehabilitation Center, LLC in Mobile, Alabama, and North Mobile Nursing and Rehabilitation Center, LLC in Eight Mile, Alabama.

151. Tara Cares' corporate office promotes a corporate culture in which Tara Pharmacy employees are expected to keep LTCFs "happy" by not delaying fulfillment of prescription drug orders, even if there are concerns about a prescription's validity. Because of the demands from the corporate office that prescriptions be dispensed immediately, many Tara Pharmacy pharmacists and staff filled what they believed to be invalid prescriptions out of a fear

of retaliation.

152. In addition, even after Relator Sproule reported his concerns that Tara Pharmacy was dispensing controlled substances pursuant to invalid prescriptions, which reports reached Tara Cares' corporate office, Tara Pharmacy continued to dispense drugs pursuant to invalid prescriptions.

B. Defendants' Practices Regarding Narcotic Boxes Violated the CSA and FCA

153. Tara Pharmacy also dispenses controlled substances to residents of Tara LTCFs through "narcotic boxes," also known as "emergency kits" and "stat boxes," located in the Tara LTCFs. Narcotic boxes contain small quantities of several drugs, including Schedule II drugs, that are intended to be used by the LTCF only in a situation where the resident encounters an emergency, as defined by 21 C.F.R. § 290.10, and there is not sufficient time to get a prescription filled by the pharmacy. Tara Pharmacy provides the drugs for the emergency kits to Tara Cares LTCFs and restocks the kits after drugs have been removed.

154. In order to properly dispense controlled substances from a narcotic box, the CSA's requirements for an emergency prescription must be met. To wit, there must be an emergency and the practitioner is required to either (1) submit a written prescription to the pharmacy or (2) give the pharmacy an oral prescription before the drug is dispensed and then provide the pharmacy with a written prescription within 7 days of dispensing the medication. Only the practitioner can issue an oral prescription.

155. Tara Cares provides staff at LTCFs with access to narcotic boxes for emergency situations but does not ensure that physicians have oral communications with a Tara Pharmacy pharmacist prior to dispensing the controlled substance. Relators estimate that there has not been oral communication between the prescribing practitioner and the pharmacy in a significant

majority of instances where drugs were dispensed from narcotic boxes including at Birmingham Nursing and Rehabilitation Center, LLC, Birmingham Nursing and Rehabilitation Center East, LLC, North Hill Nursing and Rehabilitation Center, LLC, Elba Nursing and Rehabilitation Center, LLC, Florence Nursing and Rehabilitation Center, LLC, North Mobile Nursing and Rehabilitation Center, LLC, Mobile Nursing and Rehabilitation Center, LLC, Jonesboro Nursing and Rehabilitation Center, LLC, Douglasville Nursing and Rehabilitation Center, LLC, and Lake City Nursing and Rehabilitation Center, LLC.

156. When a drug is dispensed from an emergency kit, LTCF staff fax slips to Tara Pharmacy indicating the drug has been administered. Relators saw the slips come in through DocuTrack, but knew that there had been no phone call or written order from the prescriber to the pharmacy authorizing the drug to be administered because there was no record of such an order in QS/1 or DocuTrack.

157. Tara Pharmacy would realize that drugs had been pulled without valid orders during the reconciliation process. The kit would be returned opened showing that drugs had been dispensed without a valid prescription.

158. In some cases, Relators received phone calls from LTCF staff, including nurses who might have been new employees of Tara, to inquire whether they could pull medications from the narcotics boxes without a physician. Relators would tell the nurses that they could not authorize the nurses to pull anything and instructed them to follow the procedures for verbal orders from a physician or obtain a valid prescription.

159. Nonetheless, LTCF staff pulled drugs from the narcotic boxes without a verbal order or a valid prescription and Relators would discover this through a Docutrack entry.

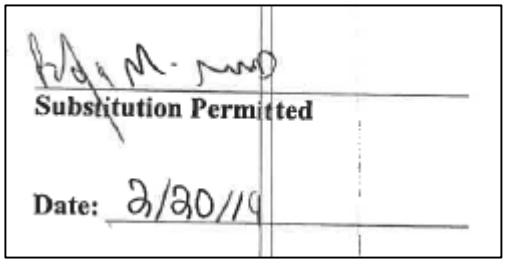
160. Once the drug was dispensed from a narcotics box without a valid order, Tara

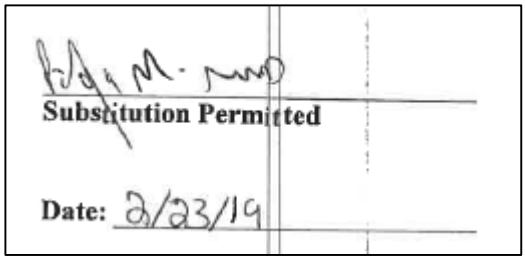
Pharmacy would seek to validate the order by requesting a written prescription. Often there would be no response to this request or in other cases, the written orders Tara Pharmacy received were invalid because they contained copied practitioner signatures.

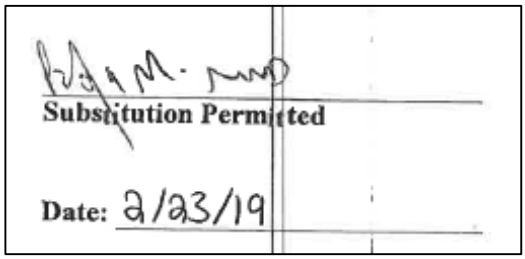
161. For example, Florence Nursing and Rehabilitation sent orders to Tara Pharmacy with Dr. Naeini's duplicate signature as purported written prescriptions for drugs that had already been removed from an emergency kit and dispensed to residents. Those orders include the following:

- A February 20, 2019 order for 1 Ativan 0.5mg tablet (a Schedule IV drug) for patient R.T.;
- A February 23, 2019 order for 1 Tramadol 50mg tablet (a Schedule IV drug) for patient R.S.;
- A February 23, 2019 order for 3 Norco 5/325mg tablets (a Schedule II drug) for patient S.R.;
- A February 23, 2019 order for 1 Ativan 0.5mg tablet for patient D.Ha.;
- An April 19, 2019 order for 1 Norco 5/325mg tablet for patient B.Ma.;
- An April 19, 2019 order for 1 Norco 5/325mg tablet and a separate order on the same day for 1 Fentanyl 25mcg transdermal patch, both for patient K.P.

These orders were not valid prescriptions for two reasons. First, Tara Pharmacy did not receive either (i) a written order from Dr. Naeini containing his valid signature before the drug was administered to the patient or (ii) an oral order from Dr. Naeini before the drug was administered to the patient. Second, the subsequent written orders did not comply with the CSA because they did not contain valid practitioner signatures. As representative examples, the following are the subsequent written orders for R.T., R.S., and S.R., respectively. They are identical to each other:







C. Defendants Acted Knowingly and Their Conduct was Materially False

162. At all relevant times, Defendants knew, deliberately ignored, or recklessly disregarded the unlawfulness of their conduct. As sophisticated health care entities, Defendants are well aware of the restrictions of the CSA and that the submission of claims to federal health care programs for reimbursement of drugs dispensed without a valid prescription violates the FCA because federal health care programs do not reimburse drugs under those circumstances.

163. It is common knowledge within the pharmacy and long-term health care facility communities that the government views abuse of controlled substances as a high enforcement priority and regularly pursues such cases.

164. For example, in 2013, the Department of Justice publicly announced that it had filed a complaint in intervention in *United States ex rel. Denk. v. PharMerica Corporation*, No.

09-cv-720 (E.D. Wis.) alleging that a long-term care pharmacy had violated the CSA and FCA by dispensing controlled substances without valid prescriptions and causing claims for those unlawfully dispensed drugs to be submitted to Medicare. The United States obtained a settlement in that matter in 2015.

165. In addition, Defendants received complaints from Relators about the unlawful behavior alleged herein, but apparently took no action to remediate such conduct, which is ongoing as of the filing of this Complaint.

166. Claims to federal health care programs for drugs dispensed without valid prescriptions are materially false. When a pharmacy such as Tara Pharmacy dispenses a drug to a federal health care program beneficiary, it submits electronic claims to the program and receives reimbursement for the costs not paid by the beneficiary.

167. In the case of Medicare beneficiaries, for example, the pharmacy submits the electronic claim to the beneficiary's Part D plan and receives reimbursement from the Part D plan sponsor. In turn, the plan sponsor notifies CMS that a drug has been dispensed through a PDE record, which includes data elements about the drug dispensed, the prescription, and the payment to the pharmacy.

168. Each PDE record submitted to CMS is a claim for payment under the FCA. Each PDE record that Part D sponsors submitted to CMS for drug transactions with Tara Pharmacy based on invalid prescriptions is a false claim that Defendants knowingly caused the sponsors to submit.

169. Defendants additionally made, used, or caused to be made or used false records and statements material to false claims. CMS regulations require that all subcontracts between Part D plan sponsors and downstream entities, such as pharmacies, contain language obligating

the pharmacy to comply with all applicable federal laws, regulations, and CMS instructions, including the CSA, the Medicare Act, and the regulations that define the requirements of a valid prescription. 42 C.F.R. § 423.505(i)(4)(iv). Through the above fraud, Defendants misrepresented their compliance with federal law as set forth in § 423.505(i). If CMS had known about the misrepresentations, it would not have approved payment to Tara Pharmacy under federal health care programs.

170. In addition, compliance with the requirement that all PDE data is true, accurate, and complete is a material condition of payment under Medicare Part D. 42 C.F.R. § 423.505(k)(3). The PDEs that Defendants have caused to be submitted to Medicare, as well as similar documents they caused to be submitted to other federal health care programs, for controlled substances dispensed without a valid prescription do not contain accurate, complete, and truthful information about all data related to payment, and are false records material to CMS's payment to the sponsor. The government, had it known the true state of affairs, would not have reimbursed such claims.

171. Defendants continue to dispense drugs to LTCF residents without valid prescriptions and thus continue to create false records or statements material to false claims to the government.

VI. CAUSES OF ACTION

Count I
Federal False Claims Act
31 U.S.C. § 3729(a)(1)(A)-(B)

172. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 171 above as though fully set forth herein.

173. This is a claim for treble damages and penalties under the False Claims Act, 31

U.S.C. §§ 3729 – 3733.

174. By virtue of the acts described above, Defendants knowingly presented, or caused to be presented, false or fraudulent claims for payment to the United States, in violation of 31 U.S.C. § 3729(a)(1)(A).

175. By virtue of the acts described above, Defendants knowingly made or used, or caused to be made or used, false records or statements to get the United States to pay or approve false or fraudulent claims, in violation of 31 U.S.C. § 3729(a)(1)(B).

176. Relators cannot now identify each of the false claims for payment that Defendants presented or caused to be presented, or the false records or statements Defendants made or used, or caused to be made or used, in support of such claims because Relators do not have access to records in Defendants' or third parties' possession.

177. The United States, unaware of the falsity of the records, statements, and claims that Defendants made or caused to be made, paid and continues to pay claims that would not be paid but for Defendants' illegal conduct.

178. Defendants have damaged, and continue to damage, the United States in a substantial amount to be determined at trial.

179. Additionally, the United States is entitled to the maximum penalty of up to $11,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990, for each and every violation alleged herein.

I. PRAYER

WHEREFORE, plaintiff prays for judgment against Defendant as follows:

1. That Defendants cease and desist from violating 31 U.S.C. § 3729(a)(1)(A)-(B);

2. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the United States has sustained because of Defendants' actions, plus a civil penalty of not less than $11,181 and not more than $22,363, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990, for each violation of 31 U.S.C. § 3729;

3. That Relators be awarded the maximum amount allowed pursuant to § 3730(d) of the Federal False Claims Act;

4. That Relators be awarded all costs of this action, including attorneys' fees and expenses; and

5. That the United States and Plaintiff-Relators recover such other and further relief as the Court deems just and proper.

REQUEST FOR TRIAL BY JURY

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff-Relators hereby demands a trial by jury.

Dated: February 18, 2020

Respectfully submitted,

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Counsel for *Qui Tam* Plaintiff-Relators

CERTIFICATE OF SERVICE

On or before this the 25th day of February, 2020, Plaintiff-Relator hereby certifies that in compliance with Rule 4 of the Federal Rules of Civil Procedure, service of the Qui Tam Complaint has been executed as follows:

By Certified Mail to:

United States Attorney for the Northern District of Alabama
Attn: Margaret Lester Marshall; Assistant United States Attorney
1801 4th Avenue North
Birmingham, Alabama 35203

By Certified Mail to:

Attorney General of the United States of America
Attn: Commercial Litigation Branch; Civil Frauds Division
Department of Justice
950 Pennsylvania Avenue, NW
Washington D.C. 20530-0001

Of Counsel