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1	M. Anderson Berry, SBN 262879 <u>aberry@justice4you.com</u>	FILED Superior Court Of Califor	rri:a
2	Leslie Guillon, SBN 222400 lguillon@justice4you.com	Sacramento	/ # ###-5g
3	CLAYEO C. ARNOLD, A PROFESSIONAL LAW CORPORATION	03/28/2019 emedina	
4	865 Howe Avenue Sacramento, CA 95825	В <u>у</u> , Dep	uty
5	Telephone: (916) 777-7777 Facsimile: (916) 924-1829	Саве Number: 34-2019-0025332	4
6 7	Attorneys for Plaintiffs-Relators		
8	SUPERIOR COURT OF CALIFORNIA		
9	COUNTY OF SACRAMENTO		
10		ACKAMENIO	
11	The State of California, ex rel [FILED UNDER	Case No.:	
12	SEAL]	COMPLAINT	
13	Plaintiffs, vs.	DEMAND FOR JURY TRIAL	
14	[FILED UNDER SEAL]	FILED UNDER SEAL	
15 16	Defendants.	(Cal. False Claims Act, Cal. Gov't Code §§ 12650, <i>et seq.</i> ) (Cal. Gov't Code § 12652(c)(2))	
17		(Cal. Insurance Frauds Prevention Act,	
18		Cal. Ins. Code §§ 1871.7, et seq.) (Cal. Ins. Code § 1871.7(e)(2))	
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22	[FILED UNDER SEAL AND CONFIDENTIAL PURSUANT TO CALIFORNIA RULES OF COURT 2.570-2.573; Cal. Gov't Code § 12652(c)(2) AND Cal. Ins. Code § 1871.7(e)(2)]		
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28		Conditionally Under Seal	
	COMPLAINT (CFCA & IFPA)		

1 2 3	M. Anderson Berry, SBN 262879 <u>aberry@justice4you.com</u> Leslie Guillon, SBN 222400 <u>lguillon@justice4you.com</u> CLAYEO C. ARNOLD, A PROFESSIONAL LAW CORPORATION				
4	865 Howe Avenue Sacramento, CA 95825 Telephone: (916) 777-777 Facsimile: (916) 924-1829				
6 7	Attorneys for Plaintiffs-Relators				
8	SUPERIOR COURT OF CALIFORNIA				
9	COUNTY OF SA	CRAMENTO			
10					
11	The State of California, ex rel Happy Baumann and Cindy Swintelski,	Case No.:			
12 13	Plaintiffs,	<u>COMPLAINT</u>			
13	vs.	DEMAND FOR JURY TRIAL			
15	The Pill Club Medical Group, Inc., The Pill Club Holdings, Inc., Mobimeds, Inc., David Svec,	FILED UNDER SEAL			
16	M.D., Inc., Roy Nicolas Chang, Sajad Zalzala, Milagros Piñon, Sandy Wang and DOES 1 thorough 25, inclusive,	(Cal. False Claims Act, Cal. Gov't Code §§ 12650, <i>et seq.</i> ) (Cal. Gov't Code § 12652(c)(2))			
17	Defendants.	(Cal. Insurance Frauds Prevention Act,			
18		Cal. Ins. Code §§ 1871.7, et seq.) (Cal. Ins. Code § 1871.7(e)(2))			
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This is an action brought on behalf of the State of California by Happy Baumann and Cindy Swintelski ("Relators"), by and through their attorneys, against The Pill Club Medical Group, Inc., The Pill Club Holdings, Inc., Mobimeds, Inc., David Svec, M.D. Inc., Roy Nicolas Chang, Sajad Zalzala, Milagros Piñon, Sandy Wang, and DOES 1 thorough 25 (collectively "The Pill Club" or "Defendants"), pursuant to the *qui tam* provisions of the California Insurance Frauds Prevention Act, California Insurance Code §§ 1871.7, *et seq*. ("IFPA") and the California False Claims Act, Cal. Gov't Code §§ 12650, *et seq*. ("CFCA").

#### I. INTRODUCTION

1. Defendants have, since at least approximately May 2016, participated in a scheme that defrauded millions of dollars from Medi-Cal and private health care insurance providers in at least 38 states, including California. Defendants knowingly and routinely presented bills to Medi-Cal and private health care insurers for patients prescribed birth control pills and related products by nurse practitioners that were not properly supervised under California law by a medical doctor. The false claims presented to the insurers include reimbursements for the contraceptives and for The Pill Club's employees' assessments, diagnoses and prescriptions, which were performed in far less time than required.

2. The Pill Club's strictly online services offer women a variety of types and brands of birth control – as well as other contraceptive including the ring (NuvaRing®), the patch (Xulane®), emergency contraceptives and female condoms. All these products are furnished by The Pill Club online through the patients' computer or smartphone. There is rarely face-to-face interaction, whether in person, by video, or even by telephone. Most everything is done by typing/texting.

3. Patients with an existing prescription can have their doctor call, fax or "eprescribe" their prescription to The Pill Club and Defendants will fill it from their "in-house pharmacy." Or these patients can simply transfer their prescription from their current pharmacy to The Pill Club pharmacy when they sign up online. These services are available in all 50 states.

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4. In 38 states, including California, the patients do not need an existing prescription for the pills or other products.<sup>1</sup> Through their computer or smartphone, patients contact The Pill Club through the website or by text. These patients without a prescription fill out a short "selfscreening tool," then certain patients – those eligible for an online prescription – are put in contact (through text or the website) with a nurse practitioner employed by Defendants.

5. The nurse practitioner ("NP") spends from approximately 15 seconds to a few minutes assessing and diagnosing the patient before prescribing the birth control. NPs are encouraged to complete an astounding 120 prescriptions per day, with some claiming they can complete 600 per day. Thus, in California alone, there could be thousands of prescriptions rubber-stamped by Defendants' NPs every single day.

6. The pharmaceuticals and other products are then delivered by mail, with no delivery charge and, depending on the health care insurer, no co-pay. The deliveries also come with "chocolate and sample gift items."

7. The NPs assessing, diagnosing and prescribing the birth control never see and rarely speak to the patients that require a prescription from The Pill Club. Communications are done through texts via the website, emails, or the rare phone call. Although that in itself is problematic, this process really facilitates the fraud, as described below.

8. Under California Business and Professions Code § 2836.1(d), a NP can diagnose and prescribe certain drugs, including contraceptives, but for patient safety concerns the NP must be supervised by a "[p]hysician or surgeon." Physician supervision does not happen at The Pill Club.

9. Although California law does not require the supervising doctor to be physically present with the NP or patient, the supervision must include the doctor's "(1) collaboration [with the NP] on the development of the standardized procedure, (2) approval of the standardized procedure, and (3) availability by telephonic contact at the time of patient examination by the

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<sup>&</sup>lt;sup>1</sup> "The Pill Club Medical Group, Inc. offers a prescribing service to these states: AL, AZ, CA, CO, CT, DC, FL, GA, HI, IA, IL, IN, KS, KY, MA, ME, MO, MN, MI, MT, NC, NE, NJ, NV, NY, OH, OR, RI, PA, SC, TN, TX, UT, VA, VT, WA, WI, WY," which equals 38 states. *See* <u>https://thepillclub.com/main/help/contact-us</u> (last visited Mar. 26, 2019).

nurse practitioner." Cal. B&P 2836.1(d). Moreover, "no physician . . . shall supervise more than four nurse practitioners at one time." Id. at 2836.1(e).

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10. To enrich themselves at the expense of Medi-Cal and private health care insurers, Defendants knowingly instructed NPs to diagnose and write an unmanageable number of prescriptions and refills for patients where those NPs: (1) had no supervising doctor; (2) had no supervising doctor licensed in California; (3) had no way to contact a supervising doctor, if one existed; (4) had no proper standardized procedures or protocols; (5) spent far less time than required assessing, diagnosing and prescribing, and/or (6) if a supervising doctor did exist, the NPs outnumbered the doctors so that the doctors would have had to supervise more than four NPs at any given time.

11. By employing NPs licensed in and outside California to prescribe contraceptives, and not employing enough physician supervision, The Pill Club increased its profits while putting women's health in danger.

12. Health care fraud of this type not only can physically hurt people, it results in higher insurance premiums for residents in the affected states who are seeking health insurance. Defendants knew, or reasonably foresaw, that violating health care laws would cause Medi-Cal and private insurers to pay millions of dollars for claims that were actually ineligible for reimbursement.

13. Relators acquired first-hand knowledge of these practices through their employment as nurse practitioners at The Pill Club.

#### II. JURISDICTION AND VENUE

14. This is a civil action arising under the laws of the State of California to redress violations of the California False Claims Act, Cal. Gov't Code §§ 12650, et seq., and the California Insurance Frauds Prevention Act, Ins. Code § 1871.7, et seq.

15. This Court has original jurisdiction over this action pursuant to California Constitution article 6, section 10.

16. This Court has jurisdiction over the subject matter of this civil claim pursuant to Cal. Gov't Code § 12650 and Cal. Ins. Code § 1871.7. 28

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17. This Court has jurisdiction over Defendants because each Defendant intentionally avails itself of the California market so as to render the exercise of jurisdiction over it by the California courts consistent with traditional notions of fair play and substantial justice.

18. The violations of law alleged in this Complaint occurred in Sacramento and many other Counties throughout California.

19. Venue is proper in this District because: (a) Defendants, or some of them, can be found, reside, or transact or have transacted business in Sacramento County; and (b) Defendants performed many of the relevant acts and omissions in Sacramento County.

III. THE PARTIES

20. Relator Happy Baumann is a citizen of the United States and a resident of Santa Clara County, California. She has been employed by The Pill Club Medical Group, Inc. and David Svec, M.D., Inc., as a nurse practitioner since on or about March 26, 2018.

21. Relator Cindy Swintelski is a citizen of the United States and a resident of Los Angeles County, California. She was employed by The Pill Club Medical Group, Inc. and David Svec, M.D., Inc., as a nurse practitioner from on or about April 23, 2018 to on or about November 27, 2018. Relators are suing on behalf of the State of California, including the California Department of Insurance, under the CFCA and the IFPA.

22. Defendant The Pill Club Medical Group, Inc., is a California corporation headquartered at 133 Arch Street, Suite 7, Redwood City, CA 94062. The President and Chief Executive Officer is Sajad Zalzala, M.D. and the Secretary is Roy Nicolas Chang. On or about September 28, 2017, David Svec, M.D., amended Article I of the Articles of Incorporation of David Svec, M.D., Inc. to include that "The name of this corporation is THE PILL CLUB MEDICAL GROUP, INC." In addition to the Arch Street address, The Pill Club Medical Group, Inc. and David Svec, M.D., Inc, share NPI # 1558801837.

23. Defendant The Pill Club Holdings, Inc., is a Delaware corporation headquartered at 969 Industrial Road, San Carlos, CA 94070, formally located at 133 Arch Street, Suite 7, Redwood City, CA 94062. The Chief Executive Officer is Roy Nicolas Chang.

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24. Defendant Mobimeds, Inc., is a Delaware corporation headquartered at 969 Industrial Road, Suite G, San Carlos, CA 94070, formally located at 133 Arch Street, Suite 7, Redwood City, CA 94062. The Chief Executive Officer, Secretary and Chief Financial Officer is Roy Nicolas Chang.<sup>2</sup>

25. Defendant David Svec, M.D., Inc., is a California corporation headquartered at 133 Arch Street, Suite 7, Redwood City, CA 94062. The President is David M. Svec, M.D.

26. Defendant Roy Nicolas "Nick" Chang is the CEO, Secretary and CFO of Defendant Mobimeds, Inc., the Secretary of Defendant The Pill Club Medical Group, Inc., and the CEO of Defendant The Pill Club Holdings, Inc. Mr. Chang is a resident of San Mateo County, California.

27. Defendant Sajad Zalzala is the President and CEO of Defendant The Pill Club Medical Group, Inc., and a purported supervising physician for Defendants nurse practitioners since in or about November 2018. Dr. Zalzala is a resident of Wayne County, Michigan, and is licensed by the Medical Board of California.

28. Defendant Milagros "Mili" Piñon has been employed by The Pill Club since May 2017, and as the Chief Operating Officer since in or about January 2018. Upon information and belief, Ms. Piñon is a resident of San Francisco County, California.

29. Defendant Sandy Wang has been Director Of Nursing Operations at The Pill Club since September 2018. Before that she was Lead Nurse Practitioner beginning in or about August 2017. Ms. Wang is a resident of Los Angeles County, California.

30. The true names or capacities, whether individual, corporate, associate or otherwise of DOES 1 through 25, inclusive, are unknown to Relators, who therefore sue such DOES by such fictitious names. Relators are informed and believe and thereon allege that each of the DOES is legally responsible in some manner for the events and happenings referenced herein.

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<sup>&</sup>lt;sup>26</sup>
<sup>2</sup> "Upon receipt of a prescription, MobiMeds, Inc. d/b/a The Pill Club can dispense to AK, AL,
<sup>27</sup>
<sup>28</sup>
<sup>28</sup> "Upon receipt of a prescription, MobiMeds, Inc. d/b/a The Pill Club can dispense to AK, AL,
<sup>27</sup> AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI,
<sup>28</sup> MN, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN,
<sup>28</sup> TX, UT, VA, VT, WA, WI, WV, WY." See <u>https://thepillclub.com/main</u> (last visited Mar. 27, 2019).

31. On information and belief, each of the Defendants was the agent, joint venture, and/or employee of each of the remaining Defendants and in doing the things alleged in the Complaint, each Defendant was acting within the scope of said agency, joint venture, and/or employment, with advanced knowledge, acquiescence, or subsequent ratification of each and every remaining Defendant.

32. Whenever reference is made in this Complaint to any act of "The Pill Club" or "Defendants," that allegation shall mean that each Defendant acted individually and jointly with the other Defendants named in that cause of action.

33. At all times mentioned herein, each of the Defendants acted as the principal, agent, or representative of each of the other Defendants, and in doing the acts herein alleged, each Defendant was acting within the course and scope of the agency relationship with each of the other Defendants, and with the permission and ratification of each of the other Defendants.

34. At all relevant times, Defendants have controlled, directed, formulated, known and/or approved of, and/or agreed to the various acts and practices of each of the Defendants.

35. At all times mentioned herein, each Defendant knew that the other Defendants were engaging in or planned to engage in the violations of law alleged in this Complaint. Knowing that other Defendants were engaging in such unlawful conduct, each Defendant nevertheless facilitated the commission of those unlawful acts. Each Defendant intended to and did encourage, facilitate, or assist in the commission of the unlawful acts alleged in this Complaint, and thereby aided and abetted the other Defendants in the unlawful conduct.

36. Each Defendant committed the acts, caused or directed others to commit the acts, or permitted others to commit the acts alleged in this Complaint. Additionally, some or all of the Defendants acted as the agents of the other Defendants, and all of the Defendants acted within the scope of their agency if acting as an agent of another.

37. All of the conduct that forms the basis for this Complaint has been undertaken by Defendants by and through their agents, employees, officers, or others acting on their behalf.

#### IV. FACTUAL ALLEGATIONS

#### A. Insurance Frauds Prevention Act

38. This action is brought under Cal. Ins. Code § 1871.7 and Cal. Penal Code § 550. Penal Code § 550 criminalizes, among other things, the act of knowingly presenting false, fraudulent or misleading claims to an insurance company, and "knowingly assist[ing] or conspire[ing] with any person" to present false, fraudulent or misleading claims to an insurance company.

39. In 1993, the California Legislature enacted the IFPA to combat insurance fraud. The Legislature recognized the "potential for abuse and illegal activities" and designed the IFPA "to permit the full utilization of the expertise of the commissioner and the department so that they may more effectively investigate and discover insurance frauds, [and] halt fraudulent activities." Cal. Ins. Code § 1871(a).

40. The Legislature also highlighted the negative impact of health insurance fraud in particular, advising that it is believed that fraudulent activities account for billions of dollars annually in added health care costs nationally. Health care fraud causes losses in premium dollars and increases health care costs unnecessarily." Cal. Ins. Code § 1871(h).

41. To combat this fraud, the IFPA permits civil enforcement of relevant provisions of the Penal Code, either by the State or by any "interested person" on behalf of the State; that is, a relator in a *qui tam* action. Specifically, section 1871.7 provides that any person who violates a provision of Penal Code §§ 549, 550, or 551, is liable for civil penalties between \$5,000 and \$10,000 for each violation, plus an assessment of not more than three times the amount of each claim for compensation, as defined in section 3207 of the California Labor Code or pursuant to the contract of insurance.

42. The IFPA allows any person having knowledge of illegal conduct as specified in § 1871.7 to bring an action and to share in any recovery. Under § 1871.7(e)(2), the complaint is to be filed under seal for 60 days (without service on the defendants) to enable the State or county government to: (1) conduct its own investigation without the knowledge of the defendants; and (2) to determine whether to intervene in the action.

43. Relator must also file the complaint and a detailed disclosure statement of substantially all material evidence and information in the relator's possession with the applicable County District Attorney and the Insurance Commissioner. Relators have complied with these requirements, set out in § 1871.7(e)(2).

44. The facts in support of this action were developed through Relators' direct and personal knowledge while employed by Defendants.

45. Relators are the original source for all of the information contained in this complaint related to Defendants. This lawsuit is not based on any public disclosure of the allegations or transactions which form the basis of the claims against the named Defendants.

#### B. California False Claims Act

46. This action is also brought under the California False Claims Act, which provides, in part, that any entity that (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; (2) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; or (3) is a beneficiary of an inadvertent submission of a false claim, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the state . . . within a reasonable time after discovery, is liable to the State of California for damages and penalties. Cal. Gov't Code § 12651(a)(1), (a)(2) and (a)(8).

47. To show that an entity acted "knowingly" under the California False Claims Act, the plaintiff must prove that the entity, with respect to information: (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information. Proof of specific intent to defraud the State of California is not required. Cal Gov't Code § 12650(b)(3).

48. The CFCA permits either the State or any "person" on behalf of the State, to bring a civil action for violations of the CFCA. Section 12651 provides that any person who violates this article is liable for civil penalties between \$5,500 and \$11,000 for each violation, plus an assessment of not more than three times the amount of damages that the state or political subdivision sustains because of defendant's false claims.

49. Under § 12652(c), the complaint is to be filed under seal for 60 days (without service on the defendants) to enable the State to: (1) conduct its own investigation without the knowledge of the defendants; and (2) to determine whether to intervene in the action.

50. Relator must also file the complaint and a detailed disclosure statement of substantially all material evidence and information in the relator's possession with the California Attorney General. Relators have complied with these requirements, set out in Cal Gov't Code § 12652(c)(3).

51. Relators, on behalf of the State of California, seek to recover damages and civil penalties arising from Defendants' violations of the CFCA and the IFPA. Specifically, Defendants knowingly and routinely presented false and fraudulent claims to Medi-Cal and private health care insurers for patients prescribed birth control pills and related products by nurse practitioners that were not properly supervised by a medical doctor under California law. The false claims caused payments from insurers for the contraceptives and The Pill Club's employees' diagnoses and prescriptions, thereby violating the CFCA and the IFPA.

## C. California Business & Professions Code

52. The California Business & Professions Code §§ 2834-2837 set out regulations for nurse practitioners practicing in California. The relevant section for this matter is § 2836.1, entitled "Furnishing Drugs or Devices."

53. Under § 2836.1, "[n]either this chapter nor any other provision of law shall be construed to prohibit a nurse practitioner from furnishing or ordering drugs or devices when all of the following apply:"

(a) The drugs or devices are furnished or ordered by a nurse practitioner in accordance with standardized procedures or protocols developed by the nurse practitioner and the supervising physician and surgeon when the drugs or devices furnished or ordered are consistent with the practitioner's educational preparation or for which clinical competency has been established and maintained.

(b) The nurse practitioner is functioning pursuant to standardized procedure, as defined by Section 2725, or protocol. The standardized procedure or protocol shall be developed and approved by the supervising physician and surgeon, the nurse practitioner, and the facility administrator or the designee.

(c)(1) The standardized procedure or protocol covering the furnishing of drugs or devices shall specify which nurse practitioners may furnish or order drugs or devices, which drugs or devices may be furnished or ordered, under what circumstances, the extent of physician and surgeon supervision, the method of periodic review of the nurse practitioner's competence, including peer review, and review of the provisions of the standardized procedure.

(d) The furnishing or ordering of drugs or devices by a nurse practitioner occurs under physician and surgeon supervision. Physician and surgeon supervision shall not be construed to require the physical presence of the physician, but does include (1) collaboration on the development of the standardized procedure, (2) approval of the standardized procedure, and (3) availability by telephonic contact at the time of patient examination by the nurse practitioner.

(e) For purposes of this section, no physician and surgeon shall supervise more than four nurse practitioners at one time.

(g)(1) The board has certified in accordance with Section 2836.3 that the nurse practitioner has satisfactorily completed a course in pharmacology covering the drugs or devices to be furnished or ordered under this section.

(h) Use of the term "furnishing" in this section, in health facilities defined in Section 1250 of the Health and Safety Code, shall include (1) the ordering of a drug or device in accordance with the standardized procedure and (2) transmitting an order of a supervising physician and surgeon.

(i) "Drug order" or "order" for purposes of this section means an order for medication which is dispensed to or for an ultimate user, issued by a nurse practitioner as an individual practitioner, within the meaning of Section 1306.02 of Title 21 of the Code of Federal Regulations. Notwithstanding any other provision of law, (1) a drug order issued pursuant to this section shall be treated in the same manner as a prescription of the supervising physician; (2) all references to "prescription" in this code and the Health and Safety Code shall include drug orders issued by nurse practitioners; and (3) the signature of a nurse practitioner on a drug order issued in accordance with this section shall be deemed to be the signature of a prescriber for purposes of this code and the Health and Safety Code. (Emphases added.)

### D. The Medi-Cal Program

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54. Title XIX of the Social Security Act of July 30, 1965 (Title 42 U.S.C. §§ 1396, et seq.) establishes a medical assistance program known as the Medicaid Program. Medicaid is a health insurance program designed to assist participating states in providing medical services to families with dependent children, to the aged, the mentally infirm, the blind, and the totally disabled, whose income and resources are insufficient to meet the costs of necessary medical

services and supplies. The Medicaid program is administered by the respective states and jointly paid for by each state and the United States Government.

55. California's Medicaid Program is known as Medi-Cal, and is administered by the California Department of Health Care Services ("DHCS" or "the Department") (formerly the California Department of Health Services). Cal. Welfare and Institutions Code §§ 14000, et seq. The Medi-Cal program is funded with 50% federal funds and 50% state funds.

56. A provider who presents a false claim to Medi-Cal presents, or causes to be presented, a false claim for payment or approval to an officer or employee of the United States and of the State of California.

57. Under the Medicaid program, states may provide optional coverage of "prescribed drugs." 42 U.S.C. § 1396d(a)(12). Prescription drugs are among the benefits provided by the Medi-Cal program. Cal. Welfare and Institutions Code § 14132(d); Medi-Cal State Plan, Attachments 3.1-A & 3.1-B, Item 12.

58. To participate in and submit claims under the Medi-Cal program, a pharmacy 14 provider must enter into a Provider Agreement with DHCS. 42 U.S.C. §1396a(a)(27); 42 C.F.R. 431.107; Cal. Welfare and Institutions Code § 14043.2; 22 C.F.R. § 51000.30{a)(2).

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59. The Provider Agreement requires the provider to agree, *inter alia*, as follows:

Compliance with Laws and Regulations. Provider agrees to comply with all applicable provisions of Chapters 7 and 8 of the Welfare and Institutions Code (commencing with Sections 14000 and 14200), and any applicable rules or regulations promulgated by DHCS pursuant to these Chapters. Provider further agrees that if it violates any of the provisions of Chapters 7 and 8 of the Welfare and Institutions Code, or any other regulations promulgated by DHCS pursuant to these Chapters, it may be subject to all sanctions or other remedies available to DHCS. Provider further agrees to comply with all federal laws and regulations governing and regulating Medicaid providers.

\* \* \*

Forbidden Conduct. Provider agrees that it shall not engage in conduct inimical to the public health, morals, welfare and safety of any Medi-Cal beneficiary, or the fiscal integrity of the Medi-Cal program.

Provider Fraud and Abuse. Provider agrees that it shall not engage in or commit fraud or abuse.

\* \* \*

Compliance with Billing and Claims Requirements. Provider agrees that it shall comply 1 with all of the billing and claims requirements set forth in the Welfare and Institutions Code and its implementing regulations, and the provider manual. 2 \* \* \* 3 Provider agrees that compliance with the provisions of this agreement is a condition precedent to payment to provider. 4 5 Medi-Cal Provider Agreement (emphasis in original). 6 60. Medi-Cal requires providers, including pharmacy providers, when submitting 7 claims, to certify that they have provided all information material to payment from state and 8 federal funds and that such information is true, accurate, and complete. 9 61. Medi-Cal billing requirements provide that each claim submitted for payment must be on a form approved by DHCS and shall include "The provider's signature certifying that 10 11 all information included on or attached to the billing form is true, accurate and complete." 22 12 Cal. Code Reg. § 51502(a)(11). 13 62. The Department's "Pharmacy Claim Form" for Medi-Cal claims includes a 14 required certification as to each claim submitted which states, in part: 15 This to certify that the information contained above is true, accurate and complete and that the provider has read, understands, and agrees to be bound by and comply with the 16 statements and conditions contained on the back of this form. 17 [Back of Form] IMPORTANT The services listed on this form have been personally 18 provided to the patient by the provider or under the provider's direction ... The services were, to the best of provider's knowledge, medically indicated and necessary to the health 19 of the patient. The provider understands that payment of this claim will be from Federal and/or State funds, and that any falsification, or concealment of a material fact, may be 20 prosecuted under Federal and/or state laws. 21 Medi-Cal Pharmacy Claim Form, Form 30-1. 22 63. Similarly, any provider submitting claims electronically must enter into an 23 agreement with the Department that claims submitted electronically are not to be processed 24 "until such time as the Department's fiscal intermediary receives, verifies and posts a Claims 25 Certification Statement and Control Sheet" which must include, inter alia, "[a] certification of 26 the truth and accuracy of each claim." 22 Cal. Code Reg. § 51502.1(f). 27 28

64. The agreement a Medi-Cal provider must enter into with the Department when obtaining permission to bill electronically, requires a Medi-Cal provider to certify, *inter alia*, as follows: The Provider shall also certify that all information submitted electronically is accurate

and complete. The Provider understands that payment of these claims will be from federal and/or state funds, and that any falsification or concealment of a material fact may be prosecuted under federal and/or state laws.

Medi-Cal Telecommunications Provider and Biller Application/Agreement.

65. Compliance with the requirement that a claim is "true, accurate, and complete" and does not falsify or conceal any fact material to payment from federal and/or state funds is a material condition of payment under the Medi-Cal program.

66. Compliance with state laws, including Cal. Business & Professions Code § 2836.1, is a material precondition for Medi-Cal payment.

67. Medi-Cal will not pay for prescription drugs unless they are prescribed by a physician or other licensed practitioner, dispensed by a licensed pharmacist or other practitioner in accordance with the State Medical Practice Act, or dispensed by the licensed pharmacist on a written prescription maintained in the pharmacist's or other practitioner's records. 42 U.S.C. § 1396d(a)(12); 42 C.F.R.440.120(a); Cal. Welfare & Inst. Code § 14170.10.

68. Medi-Cal providers agree that, as a condition of payment, they will comply with all federal and state laws and regulations governing and regulating Medicaid providers. Claims submitted to Medi-Cal for drugs dispensed illegally or without a valid prescription falsify or conceal a material fact and are not true, accurate and complete; such claims are false claims.

### E. Prescriptions and Evaluation and Management Services

69. The Pill Club not only bills Medi-Cal and private insurance companies for the drugs and devices it sells to patients, when a doctor, nurse practitioner or other health care provider diagnoses a patient to "furnish[] or order[]" a drug or device for that patient, the Defendants bill the insurance company for that service.

70. The cost to insurance companies for these services varies. For example, the
reimbursement amount for CPT codes 99212 and 99402, detailed below, ranges from
approximately \$50 to \$60.

71. Health care providers can bill Medi-Cal and private insurers for the time that they spend with a patient for initial diagnoses, prescription, and/or evaluation and management ("E/M") services for existing patients, as long as the applicable regulations are followed. These services vary with respect to, among other factors, the time the health care provider spends with the patient, as well as the complexity and severity of the health-related issues addressed by the health care provider.

72. Current Procedural Terminology ("CPT") is a medical code set that is used to 8 report medical, surgical, and diagnostic procedures and services to health insurance companies and accreditation organizations. 9

73. For example, CPT code 99402 is billed to insurance companies for prescribing contraceptives to new patients. This code covers preventive medicine counseling and/or risk factor reduction interventions provided to an individual. The average time needed to complete this is approximately 30 minutes.

74. Similarly, CPT code 99401 covers preventive medicine counseling and/or risk factor reduction interventions provided to an individual, taking approximately 15 minutes. CPT code 99403 covers preventive medicine counseling and/or risk factor reduction interventions provided to an individual, taking approximately 45 minutes. CPT code 99404 cover preventive medicine counseling and/or risk factor reduction interventions provided to an individual, taking approximately one hour.

75. To furnish or order drugs or devices for existing patients, healthcare providers bill E/M services. Health care providers must choose one of five CPT codes: 99211, 99212, 99213, 99214, or 99215. Health care providers spend, on average, 10 minutes of face-to-face time with the patient for services they bill using CPT code 99212. When physicians bill CPT code 99213, they average 15 minutes of face-to-face time with the patient. When physicians bill using CPT Code 99214, they have spent, on average, 25 minutes of face-to-face time with the patient during the office visit.

76. Other relevant CPT codes include 99381-99387 (New Patient Preventive 27 Medicine Services); 99391-99397 (Established Patient Preventive Medicine Services); 99405-28

COMPLAINT (CFCA & IFPA)

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99412 (Counseling Risk Factor Reduction and Behavior Change Intervention); and 99429 (Other Preventive Medicine Services).

## F. The Dangerous Side Effects of Birth Control Pills

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77. The birth control pill, more commonly known as "the pill," is a hormone-based method of preventing pregnancy. It is also prescribed to resolve irregular menstruation, painful or heavy periods, endometriosis, acne, and premenstrual syndrome.<sup>3</sup>

78. The pill works by preventing ovulation; that is, no egg is produced so there is nothing for the sperm to fertilize. Oral contraceptive pills contain synthetic forms of the hormones estrogen, progesterone, or both. Synthetic progesterone is called progestin. Combination pills contain progestin and estrogen.

79. According to Planned Parenthood, complications for patients taking the pill can be serious: "These include heart attack, stroke, blood clots, and liver tumors. In very rare cases, they can lead to death."<sup>4</sup>

80. More common side effects of oral contraceptives include:

- a. intermenstrual spotting;
- b. nausea;
- c. breast tenderness;
- d. headaches and migraine;
- e. weight gain;
- f. mood changes;
  - g. missed periods;
- h. decreased libido;
- i. vaginal discharge; and
- j. changes to eyesight for those using contact lenses.

 <sup>&</sup>lt;sup>26</sup>
 <sup>3</sup> See L. Smith BSN MSN CRNP, 10 Most Common Birth Control Pill Side Effects, Med. News
 <sup>27</sup>
 <sup>4</sup> See How safe is the birth control pill?, Planned Parenthood website, available at:

<sup>28 &</sup>lt;u>https://www.plannedparenthood.org/learn/birth-control/birth-control-pill/how-safe-is-the-birth-control-pill</u> (last visited Mar. 22, 2019).

#### V. THE SCHEME

#### A. Overview of the Scheme to Defraud Medi-Cal and Private Insurance Companies

81. Beginning in or about May 2016 and continuing through the present, Defendants knowingly presented false claims to Medi-Cal and private insurance companies for contraceptive drugs and devices, and for the furnishing and ordering of those drugs and devices, by a staff of NPs that had unreasonable quotas and improper physician supervision as required by California law.

82. The purpose of the scheme was for Defendants to enrich themselves at the expense of health care insurers. Defendants employed a limited number of NPs in and outside California that worked from home. Defendants pushed the NPs to spend less than two minutes diagnosing and prescribing contraceptives – for each NP to be able to bill health insurers for 120 services per day.

83. Knowing they had to employ supervising doctors available "at all times" for each set of four NPs, Defendants instead did not employ enough doctors, so that NPs had: no supervising doctor; no supervising doctor licensed in California; no way to contact a supervising doctor by telephone, if a supervising doctor existed, and/or if a supervising doctor did exist, the NPs outnumbered the doctors so that the doctors would have had more than four NPs at any given time, in violation of California Business & Professions Code § 2836.1(d) and (e).

84. Moreover, Defendants violated § 2836.1 by not having collaborative standardized procedures or protocols, as set out in § 2836.1(a)-(c), from at least approximately May 2016 through at least October 2018.

85. Violations of these laws are illegal and compliance with these provisions are material to the treatment of claims for reimbursement by Medi-Cal and private insurers. If Medi-Cal and private insurance companies had known that prescriptions from Defendants had been written because of Defendants' fraudulent scheme, Medi-Cal and private insurers would not have provided reimbursement for these prescriptions and for the related services.

#### B. Defendants' Knowledge and Roles in the Scheme

86. Using their knowledge of the applicable billing and reporting provisions, Defendants presented false, fraudulent, and misleading bills to insurance companies for payment.

Defendants submitted the false and misleading documents to various insurers in support of fraudulent, false, or misleading charges for patients that were furnished drugs or devices by Defendants' NPs that lacked the required physician supervision.

87. Relator Happy Baumann began working as a nurse practitioner, or NP, for The Pill Club on or about March 26, 2018. At that time, Defendants told Ms. Baumann her supervising physician was Dr. Carolyn J. Mannon, but Ms. Baumann did not enter into an agreement with Dr. Mannon, nor did she operate under any collaborative, standardized procedures or protocols developed by her and her supervising physician at any time.

88. Six months after starting at The Pill Club, on or about September 21, 2018, Ms. Baumann finally entered into an agreement with Dr. Mannon, entitled *Collaborative Agreement* & *Standardized Procedures*. (Exhibit A.) The agreement was backdated by almost six months to Ms. Baumann's date of hire, March 26, 2018, by Ms. Baumann's manager, Sandy Wang, in an effort to legitimize all the prescriptions and other services Ms. Baumann had performed since she was hired. (Exhibit B.)

89. Although months late, the agreement attempts to follow California Business & Professions Code §§ 2836.1(a)-(d) and (e). First, Ms. Baumann signed the agreement, therefore *approving* the "standardized procedure," as required by 2836.1(d), but she did not *collaborate* "on the development of the standardized procedure" with Dr. Mannon or Defendants, which is also required by more than one subsection of § 2836.1. In fact, the agreement states: "The Standardized Procedures [in this agreement] have been developed . . . by The Pill Club Medical Group." *Id.* at 3.

90. Second, in the section entitled "Furnishing Drugs and Devices," the "protocols" include, among other things, "A physician must be available at all times in person or by telephonic contact," which loosely follows § 2836.1(d). Next, another listed "protocol" follows § 2836.1(e), stating "Collaboration physicians will adhere to state specific requirements for NP:MD Ratio per telemedicine requirements and perform chart audits as indicated per [Board of

Medicine]."<sup>5</sup> Thus, Defendants were aware of these mandatory requirements under California law, but knowingly violated them in dealing with Ms. Baumann and the other NPs.

91. Moreover, Ms. Baumann was not given a telephone contact number or email address for Dr. Mannon, and none of Defendants' documents, policies or procedures available to Ms. Baumann and her co-workers included Dr. Mannon's telephone number, email address, or any other procedure for the NPs to contact their supervising, collaborative doctors. As California law and the purportedly collaborative agreement recognize, "[a] physician must be available at all times ... by telephonic contact." Id. at 4.

92. Ms. Baumann was never able to call Dr. Mannon or any other supervising physician. Ms. Baumann was not told by Defendants that any doctor other than Dr. Mannon was her purported supervising physician and, Ms. Baumann did not enter into agreements with any other physicians. Moreover, Dr. Mannon occasionally attended weekly team meetings, but no other doctors ever attended these meetings until Dr. Zalzala did in November 2018 (see below).

93. In addition to not being supplied Dr. Mannon's telephone number, because Ms. Baumann worked remotely and during hours she chose, Dr. Mannon was not available "at all times" that Ms. Baumann worked, as required by law. On information and belief, Dr. Mannon took days off during the year, but Ms. Baumann was not made aware of those days or times when her purported supervising physician was not available.

94. Defendants knowingly violated § 2836.1(e). Although the agreement Dr. Mannon signed along with Ms. Baumann – approximately six months after Ms. Baumann started prescribing - recognized that "Collaboration physicians will adhere to state specific requirements for NP:MD Ratio per telemedicine requirements," the 4:1 ratio was ignored in California. Even if Dr. Mannon was available by telephone, which she was not, upon information 24 and belief, Dr. Mannon had many more than four NPs to supervise at any given time up until she left The Pill Club in October 2018. On information and belief, at one point The Pill Club employed up to approximately 13 NPs in California.

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<sup>&</sup>lt;sup>5</sup> Relators have no recollection of any doctors performing audits required by Cal. Board of Medicine regulations.

95. In addition to Ms. Baumann, Relator Swintelski often worked as an NP for The Pill Club during similar hours and was purportedly supervised by Dr. Mannon. Additional California NPs including, but not limited to, Shannon Devita, Patricia McMorrow, Sandy Wang,<sup>6</sup> Lauren Drummey, Rea Sarachan., Maylin Chen, Danielle Sinkford and Cindy Adams, also worked similar hours and were purportedly supervised by Dr. Mannon while furnishing and ordering drugs and devices for new and existing patients.

96. Relator Cindy Swintelski began working as a NP for The Pill Club on or about April 23, 2018. At that time, Defendants told Ms. Swintelski her supervising physician was also Dr. Mannon, but, like her Co-Relator, Ms. Swintelski did not have the proper contact information for Dr. Mannon and did not enter into a collaborative agreement with Dr. Mannon until months later.

97. The Pill Club violated the CFCA and IFPA in dealing with Ms. Swintelski and the other NPs in the same manner as it did with Ms. Baumann.

98. Although Dr. Mannon stopped working for The Pill Club on or about October 21, 2018, The Pill Club knew she remained designated as Relators' supervising physician. For example, on October 22, 2018, Ms. Baumann billed Aetna for CPT code 99212 for furnishing a contraceptive to Patient 01. (Exhibit C.) At that time, the NPs did not know Dr. Mannon was no longer employed by Defendants, and Dr. Mannon's name still appeared as their supervising physician in *Elation*, the online program The Pill Club uses for prescribing and medical records.

99. In another example, Ms. Baumann prescribed a new patient, Patient 02, contraceptives on October 23, 2018; Blue Cross was billed for CPT code 99402 on October 30, 2018. (Exhibit D.) Dr. Mannon left The Pill Club days before, but she still appeared in *Elation* as the NPs' supervising physician. Because Dr. Mannon was supervising at least four NPs, at 120 prescriptions per day, approximately 480 prescriptions were billed per day after she was no

<sup>&</sup>lt;sup>6</sup> Although Ms. Wang was the Lead NP and then Director of Nursing, she often worked alongside the other NPs furnishing and ordering drugs and devices for patients without physician supervision, and upon information and belief, she too knowingly billed insurance companies in violation of the IFPA and CFCA.

longer employed by The Pill Club. That number, however, is probably much higher because in reality there were many more NPs working at any given time.

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100. At this point, Relators' manager, Director of Nursing Operations Sandy Wang, started scrambling. Once the NPs discovered Dr. Mannon no longer worked for The Pill Club, Ms. Swintelski pressed Ms. Wang to find out the name and contact information for their new supervising physician. Initially, Ms. Wang avoided answering the questions, but eventually Ms. Wang sent Ms. Swintelski new collaborative agreements from new doctors. Ms. Wang asked Ms. Swintelski to sign boilerplate collaborative agreements so they could be backdated to cover the time in which Dr. Mannon was not employed by The Pill Club. Ms. Swintelski, however, had never heard of the doctors. When Ms. Wang refused to supply contact information for the new doctors, Ms. Swintelski refused to sign the agreements and thereafter had no supervising physician.

101. On November 14, 2018, Ms. Wang held a video call with NPs and RNs where she introduced Dr. Zalzala as the new supervising and collaborative physician for the California NPs (Zalzala is the CEO of The Pill Club Medical Group, Inc.) As "Dr. Z" introduced himself in the video, he makes it clear that he is the new supervising/collaborative physician for the NPs, and that no other doctors fill that role. Ms. Wang corroborates this in the video when she points out that at some point in the future another doctor will be joining them "to help out with Dr. Z in terms of that clinical presence[.]" At that point and earlier, however, it is clear the NPs only dealt with Dr. Mannon and then Dr. Zalzala, neither of whom collaborated with the NPs on procedures or protocols, nor did they or The Pill Club supply NPs with proper contact information or collaborative agreements for either doctor.

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## C. <u>NPs Under Pressure to Serve an Unreasonable Number of Patients Per Day</u>

102. Two of the most common CPT codes billed by Relators and their co-workers were CPT codes 99212 and 99402. For code 99212 (furnishing drugs or devices to an existing patient), an NP should spend, on average, <u>10 minutes</u> of face-to-face time with the patient. For code 99402 (furnishing drugs or devices to a new patient), an NP should spend approximately <u>30</u> <u>minutes</u>. Two minutes is just not enough time to do a proper, legal, medical assessment and

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diagnosis, and if Medi-Cal and private insurers knew The Pill Club's NPs were spending so little time they never would have paid for those services. If insurers knew NPs spent this little time, *and* had no supervision and no proper protocols, they never would have paid for The Pill Club's services.

103. Both Relators and their co-workers were pressured on a daily basis by Defendants, including Ms. Wang, Milagros "Mili" Piñon (COO), and Nick Chang (CEO), to write more and more prescriptions per day. To write 120 per day, Ms. Wang pressured the NPs to spend no more than two minutes with each patient. Relators did not feel this was enough time to properly diagnose most cases, especially for new patients. Ms. Wang and some other NPs, however, boasted that they could write 300, 400, or even 600 prescriptions in one day. There are only 480 minutes in an 8-hour day, so Ms. Wang's claim that she wrote 600 in a day would equal more than one prescription every minute.

104. Ms. Wang told Relators that the pressure came from above; from Ms. Piñon and Mr. Chang, and that they were watching the NPs daily progress in real-time. Ms. Baumann recalls that during an online team meeting, where the team was viewing Ms. Wang's computer screen, Ms. Piñon sent Ms. Wang a message that pressured Ms. Baumann to write more prescriptions on that day.

105. Not only was Ms. Piñon monitoring the NPs, in another example, she sent a message directly to Ms. Baumann (and to other NPs individually), telling her "I know you all [sic] working hard, just if you can catch up with queues by tonight we can process those orders before month end. It will mean a lot for our company!"

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#### D. Private Insurance Companies Affected by Defendants' Fraudulent Billing

106. Defendants, and their employees, officers and agents, submitted claims for payment to Medi-Cal and private insurers that contained false, fraudulent, and misleading charges for patients that were diagnosed and/or prescribed drugs or devices by NPs that did not have proper physician supervision and other requirements as required by California law.

107. Relators are unaware of, and therefore unable to identify, the true names and identities of individuals at Defendants' entities that were responsible for actual claim

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submissions or formulating the policy of submitting these illegal charges. Moreover, due to privacy concerns, Relators cannot identify individual patients involved in the scheme.

108. The false claims were submitted to numerous private insurers and other health plans, including, upon information and belief and without limitation, some or all of the following: Aetna, Anthem Blue Cross, Assurant Health, Blue California, Blue Shield of California, Blue Cross, California Foundation for Medical Care, Capital BlueCross, CareSource, Central California Alliance for Health, Cigna Healthcare, CVS Caremark, Great West Healthcare, Health Choice Insurance Co., Health Net, Healthcare Fund of Superior California, Humana, Integrated Healthcare Administration, Pacific Source Health Plans, Physicians Mutual Insurance Company, Premier, Partnership HealthPlan of California, Tricare, United Healthcare, UnitedHealthOne, University Healthcare Marketplace, and more.

#### VI. CAUSES OF ACTION

#### <u>COUNT</u> I

# (California Insurance Frauds Prevention Act, Ins. Code § 1871.7) (Against Defendants and DOES 1 through 25)

109. Relators incorporate by reference and realleges the preceding paragraphs.

110. This is a claim for treble damages and penalties under the Insurance Frauds Prevention Act, codified at Cal. Ins. Code § 1871.7, brought by Relators for the State of California.

- 111. Penal Code § 550(a) makes it illegal to:
  - a. Knowingly present or cause to be presented any false or fraudulent claim for the payment of a loss or injury, including payment of a loss or injury under a contract of insurance.
    - b. Knowingly present multiple claims for the same loss or injury, including presentation of multiple claims to more than one insurer, with an intent to defraud.
    - c. Knowingly prepare, make, or subscribe any writing, with the intent to present or use it, or to allow it to be presented, in support of any false or fraudulent claim.

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1	d.	Knowingly make or cause to be made any false or fraudulent claim for payment
2		of a health care benefit.
3	e.	Knowingly submit a claim for a health care benefit that was not used by, or on
4		behalf of, the claimant.
5	112.	Violations of these laws are illegal and compliance with these provisions are
6	material to the treatment of claims for reimbursement by private insurers. If private insurance	
7	companies had known that prescriptions from Defendants had been written because of	
8	Defendants' fraudulent scheme, insurers would not have provided reimbursement for these	
9	prescriptions or for the related services.	
10	113.	Penal Code § 550(b) makes it illegal to "knowingly assist or conspire with any
11	person" to do	any of the following:
12	f.	Present or cause to be presented any written or oral statement as part of, or in
13		support of or opposition to, a claim for payment or other benefit pursuant to an
14		insurance policy, knowing that the statement contains any false or misleading
15		information concerning any material fact.
16	g.	Prepare or make any written or oral statement that is intended to be presented to
17		any insurer or any insurance claimant in connection with, or in support of or
18		opposition to, any claim or payment or other benefit pursuant to an insurance
19		policy, knowing that the statement contains any false or misleading information
20		concerning any material fact.
21	114.	Insurance Code § 1871.7(b) provides that every person who violates Penal Code
22	§ 550 is subject to civil penalties of between \$5,000 and \$10,000, plus an assessment of not more	
23	than three times the amount of each claim for compensation.	
24	115.	By virtue of the acts described above, Defendants violated the IFPA.
25	116.	Defendants submitted false, fraudulent or misleading bills for drugs, devices and
26	related servic	es to insurance companies in all 50 states, including California.
27	117.	As a result of the above-described conduct, the State of California is entitled to
28	damages as provided for by Cal. Ins. Code § 1871.7.	
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#### COUNT II

#### (Declaratory and Injunctive Relief, Ins. Code § 1871.7(b))

#### (Against Defendants and DOES 1 through 25)

118. Relators incorporate by reference and realleges the preceding paragraphs.

119. Insurance Code § 1871.7(b) empowers the Court "to grant other equitable relief, including temporary injunctive relief, as is necessary to prevent the transfer, concealment, or dissipation of illegal proceeds, or to protect the public."

120. Relators seek equitable relief under Ins. Code § 1871.7(b), because unless equitable relief is granted, Defendants are likely to continue their unlawful conduct after the conclusion of this litigation. The State of California will continue to suffer damage if Defendants continue their fraudulent activities, as health insurance rates will continue to increase more than they otherwise would or should.

#### <u>COUNT</u> III

#### (California False Claims Act, Cal. Gov't Code § 12651(a)(1))

#### (Against Defendants and DOES 1 through 25)

121. Relators incorporate by reference and realleges the preceding paragraphs.

122. This is a claim for treble damages and penalties under the California False Claims Act, Cal. Gov't Code §§ 12650, *et seq.*, as amended.

123. By virtue of the acts described above, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to an officer or employee of the State of California and other state entities for payment or approval.

124. The false claims were material to the State of California's and other state entities' payment decisions and caused the State of California and other state entities to pay claims which would not have been paid, and to pay Defendants amounts in excess of what would have been paid, had the claims not been false.

125. By reason of these payments, the State of California and other state entities have been damaged, and continue to be damaged, in substantial amount.

1	<u>COUNT</u> IV		
2	(California False Claims Act, Cal. Gov't Code § 12651(a)(2))		
3	(Against Defendants and DOES 1 through 25)		
4	126. Relators incorporate by reference and realleges the preceding paragraphs.		
5	127. This is a claim for treble damages and penalties under the California False Claims		
6	Act, Cal. Gov't Code §§ 12650, et seq., as amended.		
7	128. By virtue of the acts described above, Defendants knowingly made, used, or		
8	caused to be made or used material false records or statements to get a false claim paid or		
9	approved by the State of California and other state entities, and that were material to false or		
10	fraudulent claims.		
11	129. The false records or statements were material to the State of California's and other		
12	state entities' payment decisions and caused the State of California and other state entities to pay		
13	claims which would not have been paid, and to pay Defendants amounts in excess of what would		
14	have been paid, had the records or statements not been false.		
15	130. By reason of these payments, the State of California and other state entities have		
16	been damaged, and continue to be damaged, in substantial amount.		
17	<u>COUNT</u> V		
18	(California False Claims Act, Cal. Gov't Code § 12651(a)(8))		
19	(In the Alternative, Against Defendants and DOES 1 through 25)		
20	121 Deleters in concerts her reference and well-see the more dimensions when		
21	<ul> <li>131. Relators incorporate by reference and realleges the preceding paragraphs.</li> <li>132. This is a slaim for trable demographic and realities under the California False Claims.</li> </ul>		
22	132. This is a claim for treble damages and penalties under the California False Claims		
23	Act, Cal. Gov't Code §§ 12651, et seq., as amended.		
24	133. By virtue of the acts described above, Defendants were beneficiaries of		
25	inadvertent submissions of false claims to the State of California and other state entities,		
26	subsequently discovered the falsity of the claims, and failed to disclose the false claims to the		
27	State of California and other state entities within a reasonable time after discovery of the false		
28	claims.		

134. The false claims were material to the State of California's and other state entities'		
payment decisions and caused the State of California and other state entities to pay claims which		
would not have been paid, and to pay Defendants amounts in excess of what would have been		
paid, had the claims not been false.		
135. By reason of Defendants' conduct, the State of California and other state entities		
have been damaged, and continue to be damaged, in substantial amount.		
VII. PRAYER FOR RELIEF		
WHEREFORE, the State of California prays for judgment against Defendants as follows:		
a. Judgment in an amount equal to three times the amount of each claim for		
compensation submitted by the Defendants from the commencement of the statutory		
period;		
b. A civil penalty of up to \$10,000 for each violation of Insurance Code § 1871.7 from		
the commencement of the statutory period;		
c. A civil penalty of up to \$11,000 for each violation of Cal. Gov't Code § 12651 from		
the commencement of the statutory period;		
d. Disgorgement of profits unlawfully acquired by Defendants;		
e. An award to Relators of the maximum amount allowed under Insurance Code §		
1871.7 and Cal. Gov't Code § 12652(g);		
f. An award of attorneys' fees, expenses and costs of suit herein incurred, under		
Insurance Code § 1871.7 and Cal. Gov't Code § 12652(g)(8);		
g. An injunction against each of the Defendants for any continuing conduct violating		
Insurance Code § 1871.7 and Cal. Gov't Code §§ 12650, et seq.;		
h. An order directing Defendants to cease and desist from violating California		
Insurance Code § 1871.7 and Cal. Gov't Code §§ 12650, et seq.;		
i. Granting Relators, the State of California and other state entities all other relief as		
the Court deems just and proper.		
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COMPLAINT (CFCA & IFPA)

Date: March 28, 2019 CLAYEO C. ARNOLD A Professional Law Corporation By: M Anderson Berry, Esq. Attorney for Relators .18 COMPLAINT (CFCA & IFPA) 

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## **COLLABORATIVE AGREEMENT & STANDARDIZED PROCEDURES**

#### INTRODUCTION TO THE STANDARDIZED PROCEDURES

The purpose of these Standardized Procedures is to define the scope of practice of the Nurse Practitioners at The Pill Club in order to meet the legal requirements for the provision of health care by nurse practitioners. They are established to assist all health care providers with an understanding of the role and scope of practice of the nurse practitioner and to provide a safeguard so that providers and patients alike may be assured of the best health care possible.

These Standardized Procedures are based on the Guidelines established by the Board of Registered Nursing and the codes and regulations circumscribing nurse practitioners in states they are actively licensed in (collectively referred to as the Nursing Practice Act). In order to provide the highest standard of care, these Standardized Procedures incorporate the following qualities:

- ADAPTABILITY--In order to allow for the unique management needs of each individual patient
- **FLEXIBILITY--** To accommodate the rapidly changing and complex nature of the healthcare field and to acknowledge that medicine is not an exact science
- PRACTICALITY—In order to be useful in a setting that must incorporate a variety of educational backgrounds and personal management styles
- **SPECIFICITY**—To address the intent of the Standardized Procedure Guidelines and codes regulating nurse practitioners and to protect the health care consumer.

#### The Standardized Procedures consist of the following:

**GENERAL POLICIES**: Define the general conditions of and give authorization to the nurse practitioner to implement the Standardized Procedures.

**HEALTH CARE MANAGEMENT STANDARDIZED PROCEDURES**: Delineate the medical functions requiring a standardized procedure and, using policies and protocols, define the circumstances and requirements for their implementation by the nurse practitioner.

#### **GENERAL POLICIES**

It is the intent of this document to authorize the Nurse Practitioner(s) at The Pill Club to implement the Standardized Procedures without the immediate supervision or approval of a physician. The Standardized Procedures, including all the policies and protocols, are defined in this document and will be referred to generally as the "Standardized Procedures".

#### DEVELOPMENT, APPROVAL, REVISION AND REVIEW

The Standardized Procedures have been developed and approved by The Pill Club Medical Group.

Review, and if necessary, revision, of the Procedures will be done annually by Nursing Leadership. The completion of these tasks, including notification of revisions, is the responsibility of the specified Nurse Practitioner(s) indicated per signature on this agreement.

#### AGREEMENT

All nurse practitioners and collaborating physicians will signify agreement to the Standardized Procedures following the approval process. Signature on the Statement(s) of Approval and Agreement implies the following: approval of all the policies and protocols in this document, the intent to abide by the Standardized Procedures, and the willingness to maintain a collegial and collaborative relationship with all the parties.

#### **SETTING**

The nurse practitioners will perform these Standardized Procedures at their designated location(s) providing telemedicine to patients requesting our services.

#### **RECORD OF AUTHORIZED NURSE PRACTITIONERS**

The Statement of Approval and Agreement signed by the nurse practitioners will act as the record of nurse practitioners authorized to implement the Standardized Procedures.

#### EDUCATION, TRAINING, AND REQUIREMENTS

The nurse practitioners must have the following:

- Master's of Science in Advanced Practice Nursing
- Bachelor's Degree in Nursing
- Valid Driver's License or proof of identity (U.S. Passport)
- Certification by the State they are actively licensed to prescribe by the Board of Registered Nursing as a Registered Nurse & Nurse Practitioner
- Furnishing Number
- DEA Number
- Certifications (if applicable)

#### **EVALUATION OF CLINICAL CARE**

Evaluation of the nurse practitioner will be provided in the following ways:

#### **INITIAL EVALUATION**

- Chart Review based on written criteria
- Informal evaluation during consultations
- Feedback from co-workers
- Evaluation throughout training and monthly to monitor adherence to company standards

#### CONTINUING EVALUATION

- Annual evaluation based on written criteria including chart review
- Verification of Continuing Education
- Verification of current certifications

- Maintaining current licensure in states actively prescribing in
- Weekly Medical Team meetings to keep team informed with Evidence Based Changes, Current Practice, etc.

#### PATIENT RECORDS

The nurse practitioner will be responsible for the preparation of a complete medical record for each patient contact per existing office policies (documentation of SOAP progress note, prescriptions for contraception, emergency contraception, female condoms, etc.).

#### PHYSICIAN SUPERVISION

The nurse practitioner is authorized to implement the Standardized Procedures in this document without the direct or immediate observation, supervision or approval of a physician, except as may be specified on individual Health Care Management Standardized Procedures. Physician consultation is available at all times, either on-site or by electronic means.

#### **CONSULTATION**

The nurse practitioner will be providing health care as outlined in this document. In general, communication physician will be sought for all the following situations, and any others deemed appropriate. Whenever a physician is consulted, a notation to that effect, including the physician's name, time and date communication occured, as well as, details of rapport, must be made in the chart.

- Whenever situations arise which go beyond the intent of the Standardized Procedures or the competence, scope of practice, or experience of the nurse practitioner
- · Whenever patient conditions fail to respond to the management plan as anticipated
- Any patient with acute decompensation or rare condition
- Any patient conditions which do not fit the commonly accepted diagnostic patterns for a disease or disorder
- At the patient's, nurse practitioner's or physician's request.
- All emergency situations after initial stabilizing care has been started.

Please consult your Senior Lead Nurse Practitioners and Director of Nursing for better guidance in this workflow.

#### HEALTH CARE MANAGEMENT STANDARDIZED PROCEDURES

#### POLICY

Family planning in the area of primary care includes counseling, treatment, and management of contraception. The nurse practitioner is authorized to diagnose and manage contraception care under the following protocols:

#### PROTOCOLS

- 1) Record patient history and review self-screening tool. Determine, using the most recent US MEC Guide to Contraceptive Use, the USMEC category of patient risk.
- 2) Reconcile medications list and verify interactions, side effects, and any potential safety concerns.
- Assessment and treatment plan is developed based on the resources and guidelines listed in this document. Refer to supervising physician or patient's PCP should the nurse practitioner determine patient as not a candidate for self-administered hormonal contraception.
- 4) E-prescribe appropriate contraception via Elation EHR to pharmacy to be dispensed. Document any special instructions prior to sending.
- 5) Provide counseling, education, and follow up instructions appropriate for the patient
- 6) Document encounter fully and completely on Elation EHR.
- 7) All other applicable Standardized Procedures in this document are followed during health care management.
- 8) Provide patient centric care through telemedicine while maintaining highest quality of practice.
- 9) All General Policies regarding Review, Approval, Setting, Education, Evaluation, Patient Records, Supervision and Consultation in these Standardized Procedures are in force.

#### **INCLUSION CRITERIA**

Females, less than 44 years of age, who do not meet any of the exclusion criteria below who are seeking hormonal contraception therapy for the purposes contraception is indicated for.

#### **EXCLUSION CRITERIA**

Patients with the following medication conditions or combination of situations are excluded from eligibility from this protocol due to limitations in telemedicine. Patients must be referred to their gynecologist or primary care physician to determine eligibility of contraception and obtain a prescription if determined to be eligible by their physician:

- Medical history of Diabetes for 20+ years and/or any diabetes-related complications
- History of heart attack or stroke
- Heart conditions (vascular disease, ischemic heart disease, atherosclerosis, valvular heart disease, high cholesterol)
- Blood clot in the legs or lungs, clotting disorder or at risk for developing blood clots.
- Inflammatory bowel disease (Ulcerative Colitis & Crohn's disease)
- Major surgery recently or in the last 6 weeks
- Personal history of breast cancer
- Liver issues (cirrhosis, gallbladder issues, liver tumors, hepatitis)
- Lupus
- Organ transplant
- PCOS
- Advised by a medical professional not to take hormones
- Blood pressure with systolic and diastolic reading >140/90
- Presence of multiple cardiovascular risk factors (smoking, diabetes, hypertension)
- Peripartum cardiomyopathy
- Less than 21 days postpartum or <42 days postpartum with venous thromboembolism (VTE) risk factors
- Smoker age 35 or older (Candidate for Progestin-Only Pill)
- Bariatric Surgery (Candidate for Patch or Ring)
- Complicated organ transplant patient
- Systemic Lupus Erythematosus (SLE) with positive or unknown antiphospholipid antibodies
- Thrombogenic mutations
- Perimenopausal and/or Menopausal patients
- Disclosure of healthcare provider advising against hormonal therapy
- History of sterilization (tubal ligation)
- Male sex\*
- Transexual/Transgender Hormone Therapy\*
- Hormone Replacement\*
- Patients on any of the following medications: ritonavir-boosted protease inhibitors, rifampicin or rifabutin, phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine, lamotrigine, antiretroviral therapy

\*Indicates these patients are referred to our pharmacy to provide education regarding having prescription transferred to receive our services in which we do not prescribe for.

# FURNISHING DRUGS AND DEVICES

## POLICY

The nurse practitioner is authorized to Furnish drugs and devices under the following protocols:

# PROTOCOLS

1) The nurse practitioner has a current Furnishing number.

- 2) The nurse practitioner has an active DEA number.
- 3) The Standardized Procedure was developed and approved in collaboration with a physician, nurse practitioner and facility administrator, or the designee.
- 4) All drugs and devices ordered are limited to the Formulary or per the recommendations in the Resources listed in this document.
- 5) The drugs and devices ordered are consistent with the nurse practitioner's educational preparation or for which clinical competency has been established and maintained.
- 6) The drug or device ordered is appropriate to the condition being treated.
- 7) Patient education is given regarding the drug or device.
- 8) The name, title, and Furnishing number of the nurse practitioner is written on the transmittal order.
- 9) The Statement of Approval and Agreement signed by the nurse practitioners will act as the record of nurse practitioners authorized to Furnish.
- 10) Collaboration physicians will adhere to state specific requirements for NP:MD Ratio per telemedicine requirements and perform chart audits as indicated per BOM.
- 11) A physician must be available at all times in person or by telephonic contact.
- 11) All other applicable Standardized Procedures in this document are followed during health care management.
- 12) All General Policies regarding Review, Approval, Setting, Education, Evaluation, Patient Records, Supervision and Consultation in these Standardized Procedures are in force.

### ORDERING SCHEDULED CONTROLLED SUBSTANCES

### POLICY

The nurse practitioner is not authorized to order scheduled controlled substances.

# **MEDICATION MANAGEMENT**

## POLICY

The nurse practitioner is authorized to manage drugs and devices under the following protocols:

## PROTOCOLS

- 1) The management of drugs or devices includes evaluating, initiating, altering, discontinuing, furnishing, and ordering of prescriptive and over-the-counter medications.
- 2) Medication evaluation includes assessment of:
  - Other medications being taken.
  - Prior medications or contraception used for current condition.
  - Medication allergies and contraindications
- 4) The drug or device is appropriate to the condition being treated, and:
  - Accepted dosages per references.
  - Generic medications are ordered if appropriate.
- 5) A plan for follow-up and refills is written in the patient's chart.
- 6) The prescription must be written in patient's chart including name of drug, strength, instructions and quantity, and signature of the nurse practitioner.
- 7) All other applicable Standardized Procedures in this document are followed during health care management.
- 8) All General Policies regarding Review, Approval, Setting, Education, Evaluation, Patient Records, Supervision and Consultation in these Standardized Procedures are in force.

## In House Protocols:

- Formulary: Any combined oral contraception, progestin-only contraception, vaginal ring, patch, and emergency contraception.
- Non-Formulary: IUDs, implants, or Depo Provera injections.

2016 U.S Medical Eligibility Criteria for Contraception Use Chart (USMEC) <u>https://www.cdc.gov/reproductivehealth/unintendedpregnancy/pdf/legal\_summary-chart\_english\_final\_tag508.pdf</u>

2016 U.S. Selected Practice Recommendations for Contraceptive Use <a href="http://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6504.pdf">http://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6504.pdf</a>

# HORMONAL CONTRACEPTION SELF-SCREENING TOOL QUESTIONS Name (Last Name, First Name)

Date of Birth (Month, Day, Year) \_\_\_\_\_

Height (inches) \_\_\_\_\_\_Weight (pounds) \_\_\_\_\_

#### HORMONAL CONTRACEPTION SELF-SCREENING TOOL QUESTIONS

1	What was the first date of your last menstrual period?	111	7
2	Have you ever taken birth control pills, or used a birth control patch, ring, or shot/injection? (If no, go to question 3)	Yes 🗆	No 🗆
	Did you ever experience a bad reaction to using hormonal birth control?	Yes 🗗	No 🗆
	Are you currently using birth control pills, or a birth control patch, ring, or shot/injection?	Yes 🖸	No 🗖
3	Have you ever been told by a medical professional not to take hormones?	Yes 🗖	No 🖸
4	Do you smoke cigarettes?	Yes 🗋	No 🖸
5	Do you think you might be pregnant now?	Yes 🗆	No 🗇
6.	Have you given birth within the past 6 weeks?	Yes 🛛	No 🖸
7	Are you currently breastfeeding an infant who is less than 1 month of age?	Yes 🖸	No 🗆
8	Do you have diabetes?	Yes 🖸	No 🗆
9	Do you get migraine headaches; or headaches so bad that you feel sick to your stomach, you lose the ability to see, it makes it hard to be in light, or it involves numbress?	Yes 🖸	No 🗆
10	Do you have high blood pressure, hypertension, or high cholesterol?	Yes 🖸	No 🗆
11	Have you ever had a heart attack or stroke, or been told you had any heart disease?	Yes 🖸	No 🗖
12	Have you ever had a blood clot in your leg or in your lung?	Yes 🖸	No 🗆
13	Have you ever been told by a medical professional that you are at a high risk of developing a blood clot in your leg or in your lung?	Yes 🛛	No 🗔
14	Have you had bariatric surgery or stomach reduction surgery?	Yes 🗆	No 🗔
15	Have you had recent major surgery or are you planning to have surgery in the next 4 weeks?	Yes 🖸	No 🖸
16	Do you have or have you ever had breast cancer?	Yes 🗆	No 🖸
17	Do you have or have you ever had hepatitis, liver disease, liver cancer, or gall bladder disease, or do you have jaundice (yellow skin or eyes)?	Yes 🗆	No 🗆
18	Do you have lupus, rheumatoid arthritis, or any blood disorders?	Yes 🗆	No 🗆
19	Do you take medication for seizures, tuberculosis (TB), fungal infections, or human immunodeficiency virus (HIV)?	Yes 🗆	No 🗆
	If yes, list them here:		
20	Do you have any other medical problems or take regular medication?	Yes 🗆	No 🖸
	If yes, list them here:		

### **21. Which method of birth control do you prefer?** \*

- Pill, answer next question
- Ring Skip to question 15a.
- 22. Do you have a specific type or brand preference? \*

No

Yes What brand?



23. Do you want to have oral emergency contraception available in addition to your regular contraception?  $\Box$ 

Yes
 No



## STATEMENT OF APPROVAL FOR COLLABORATIVE AGREEMENT

This document was jointly developed and approved by The Pill Club - Medical Group, in accordance with the codes regulating nursing practice, on the date indicated and acknowledged below.

Signature on this statement implies:

- Approval of the Standardized Procedures and all the policies and protocols contained in the collaborative agreement
- Agreement to maintain a collaborative and collegial relationship.
- Agreement to abide by the Standardized Procedures in theory and practice. ۰

**DocuSigned by:** 

Happy Baumann **Nurse Practitioner Signature** 

03-26-2018

Date\*

**FNP-C** Happy Baumann

**Printed Name/Title** 

Licensure State / License # / Expiration Date	CA	/20919	/ 05/31/2020
DEA # / Expiration Date	DEA#M	B4714487	/ 07/31/2020
Carolyn () Mannon		03 26 2018	

03-20-2010

**Physician Signature** 

Date will be postmarked to reflect date of initial hire

Carolyn Mannon, MD

**Printed Name/Title** 

Licensure State / License # / Expiration Date	CA	/ A75180	/ 09/30/2020
DEA # / Expiration Date	BM7493947	/ 01/31/2019	

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Happy Baumann <happy.baumann@thepillclub.com>

# Please DocuSign: SIGNEDCollaborativeAgreement\_DrMannon\_FINAL.pdf

1 message

Monica Moncada via DocuSign <dse\_NA3@docusign.net> Reply-To: Monica Moncada <monica.moncada@thepillclub.com> To: Happy Baumann <happy.baumann@thepillclub.com> Fri, Sep 21, 2018 at 3:33 PM



Monica Moncada sent you a document to review and sign.

# **REVIEW DOCUMENT**



Monica Moncada monica.moncada@thepillclub.com

Good afternoon,

Here is your Collaborative Agreement with Dr. Mannon. Please review/sign the document. Upon signing, you and Dr. Mannon will automatically receive a copy. Please note that the date is postmarked to your initial start date.

Let me know if you have any questions or concerns.

Best,

Monica S Moncada

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