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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, *et al.* *ex rel*. MARTINEZ, Plaintiffs, v. APRIA HEALTHCARE GROUP, INC. and APRIA HEALTHCARE LLC, Defendants	17 Civ. 1059 (ER) **COMPLAINT-IN-INTERVENTION OF THE UNITED STATES**
UNITED STATES OF AMERICA, Plaintiff-Intervenor, v. APRIA HEALTHCARE GROUP, INC. and APRIA HEALTHCARE LLC, Defendants	

The United States, by its attorney, Audrey Strass, the Acting United States Attorney for the Southern District of New York, alleges for its complaint-in-intervention as follows:

PRELIMINARY STATEMENT

1. This is a civil fraud action brought by plaintiff-intervenor the United States of America (the "Government") against defendants Apria Healthcare Group, Inc. and Apria Healthcare LLC (together, "Apria" or "Defendants") to recover damages and civil penalties

arising from Apria's violations of the False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq.*, in connection with the rental of non-invasive ventilators ("NIVs") – such as the Trilogy brand manufactured by Phillips Respironics and the Astral brand manufactured by ResMed – to patients covered by Medicare, Medicaid, TRICARE, and Federal Employees' Health Benefit Programs ("FEHBP" and, together with Medicare, Medicaid, and TRICARE, the "Federal health programs").

2. NIVs are a type of respiratory equipment designed to deliver pressurized air into the lungs of patients with chronic respiratory failure. More specifically, NIVs help patients maintain targeted tidal volume (the volume of air inhaled and exhaled with each breath) by automatically adjusting the level of pressure support provided. Patients frequently rent NIVs for regular use in their homes. During the relevant period, Medicare and other Federal health programs reimbursed durable medical equipment ("DME") providers like Apria as much as $1,400 per month for supplying NIV rentals to beneficiaries.

3. Apria engaged in three schemes in violation of the FCA. Specifically, during the period of January 1, 2014, through December 31, 2019 (the "relevant period"), Apria submitted false claims to the Federal health programs to seek reimbursement for NIV rentals: (a) when the NIVs were not medically necessary or reasonable due to the lack of continued use or continued need; (b) when certain Astral NIVs, which were only to be used in a bi-level pressure support setting called Pressure Assist Control ("PAC") mode, were not medically necessary or reasonable; or (c) where Apria induced Medicare and TRICARE beneficiaries to rent, or healthcare providers to prescribe, NIVs by waiving the required coinsurance payments ("co-pays") without individualized determinations of financial need in violation of the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b).

4. When DME providers rent NIVs to Federal health program beneficiaries and seek reimbursement for such rentals, the DME providers must ensure that the NIVs are medically necessary and reasonable (the "medical necessity requirement"). The medical necessity requirement places a responsibility on DME providers like Apria to verify that program beneficiaries continue to use their NIVs and have a continued need for the NIVs. Apria understood that it needed to comply with this aspect of the medical necessity requirement in order to bill the Federal health programs for NIV rentals. Apria also knew that patients need to use their NIVs in order to receive the benefits of NIV therapy.

5. Apria, however, often lacked information about whether patients continued to use and need their NIVs because its respiratory therapists ("RTs") failed to conduct regular visits to the patients. Apria nonetheless regularly continued to seek monthly payments from the Federal health programs for these NIV rentals. Further, even when Apria had information from RT visits indicating that patients had stopped using their NIVs, Apria often continued to seek payments from the Federal health programs – at the rate of $1,000 or more per month or $12,000 or more in a year – for NIV rentals that were not being used and not medically necessary.

6. In addition, Apria rented Astral NIVs to beneficiaries solely to provide bi-level or constant pressure support therapy, even though such PAC mode therapy could be provided by other types of respiratory equipment that were significantly less expensive than NIVs. Apria encouraged its sales staff to urge physicians to order the Astral model NIVs for patients even through the patients' medical needs could be met by less costly non-NIV devices. Apria rented the more expensive – and not medically necessary – Astral NIVs to a number of Federal health program beneficiaries and billed the programs for those costly NIV rentals.

7. Finally, Apria understood that the AKS prohibits offering to waive co-payments if one purpose of the offer is to induce physicians or patients to order or rent NIVs or other

equipment. Yet, its branch managers directed salespeople to offer co-pay waivers to influence a number of patients to rent NIVs from Apria instead of another DME supplier. Apria also discussed the possibility of waiving co-pays with patients who were not regularly using their NIVs and wished to cancel their rentals to sway those patients to continue renting the machines from Apria. In addition, Apria gave co-pay waivers to hundreds of Medicare and TRICARE beneficiaries who had NIV rentals without making an assessment as to whether those patients could have afforded some portion of their co-pay responsibilities.

8. By engaging in the above-referenced conduct in connection with the rental of NIVs, Apria submitted thousands of false claims to the Federal health programs in violation of the FCA and improperly obtained millions of dollars in payments.

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction over the Government's FCA claims pursuant to 28 U.S.C §§ 1331 and 1345.

10. This Court may exercise personal jurisdiction over Defendants. Further, because Defendants transact business in this District and provided NIV rentals to patients in this District, venue is proper in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b)–(c).

THE PARTIES

11. Plaintiff is the United States of America. Through its agencies, the Government administers the Federal health programs at issue in this action. More specifically, the Centers for Medicare and Medicaid Services ("CMS"), a component within the U.S. Department of Health and Human Services ("HHS"), administers the Medicare and Medicaid programs; the U.S. Department of Defense ("DOD") administers the TRICARE program; and the U.S. Office of Personnel Management ("OPM") administers the FEHBP.

12. Defendants are two Delaware corporations that have their principal place of business in Lake Forest, California. During the relevant period, Defendants operated approximately 300 branch offices under the "Apria Healthcare" brand, including branches in New York City, Chicago, Dallas-Fort Worth, Denver, and Miami and/or their surrounding areas. Through those branch offices, Defendants operated their DME rental business nationwide, including, as relevant here, renting NIVs to thousands of Federal health program beneficiaries.

RELEVANT BACKGROUND

I. THE FALSE CLAIMS ACT AND THE ANTI-KICKBACK STATUTE

13. The FCA was originally enacted in 1863 to address fraud on the Government in the midst of the Civil War, and it reflects Congress's long-standing objective to "enhance the Government's ability to recover losses sustained as a result of fraud against the Government." *See* S. Rep. No. 99-345, at 1 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266.

14. As relevant here, the FCA establishes treble damages liability to the Government where an individual or entity:

> (A) "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1)(A); or
>
> (B) "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim, *id*. § 3729(a)(1)(B).

31 U.S.C. § 3729(a)(1)(A)-(B).

15. "Knowingly," within the meaning of the FCA, is defined to include a defendant acting in reckless disregard or deliberate indifference of the truth or falsity of information, as well as actual knowledge of such falsity by defendant. *See id*. § 3729(b)(1).

16. In addition to treble damages, the FCA also provides for assessment of a civil

penalty for each violation or each false claim.[1]

17. The AKS makes it illegal for individuals or entities to knowingly and willfully "offer[] or pay[] remuneration (including any kickback, bribe, or rebate) . . . to any person to induce such person . . . to purchase, . . . order, . . . or recommend purchasing . . . or ordering any good . . . or item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2). Violation of the AKS is a felony punishable by fines and imprisonment and can also result in exclusion from participation in federal healthcare programs. 42 U.S.C. § 1320a-7b(b)(2); 42 U.S.C. § 1320a-7(b)(7).

18. The AKS was enacted due to congressional concern that remuneration given to those involved with making healthcare decisions would result in goods and services being provided that are not medically necessary or are of poor quality or even harmful to vulnerable patient populations.

19. To protect federal healthcare programs from such harms, Congress enacted a prohibition against the offer or payment of any "remuneration" to "induce" any referral, order, or recommendation for any type of healthcare item or service. *See* 42 U.S.C. § 1320a-7b(b)(2). For purposes of the AKS, remuneration includes anything of value.

20. Compliance with the AKS is a condition of payment for Medicare, Medicaid, and TRICARE, which are defined as "Federal health care programs" for purposes of the AKS. *See id*. § 1320a-7b(f).

21. In 2010, Congress enacted legislation to specify that a violation of the AKS gives rise to liability under the FCA. *See* Pub. L. No. 111-148, § 6402(f), 124 Stat. 119. Specifically,

[1] Under the FCA, as adjusted by applicable federal laws and regulations, civil penalties for violations occurring between September 29, 1999, and November 1, 2015, are $5,500 to $11,000, *see* 28 U.S.C. § 2461 (notes); 64 Fed. Reg. 47,099, 47,103 (1999); and civil penalties for violations occurring after November 1, 2015, are $10,781 to $21,563 *see* 82 Fed Reg. 9,131, 9,136 (2017).

pursuant to in the Patient Protection and Affordable Care Act of 2010 ("PPACA"), "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g).

22. According to the legislative history of the PPACA, this amendment to the AKS is intended to clarify "that all claims resulting from illegal kickbacks are considered false claims for the purpose of civil actions under the False Claims Act, even when the claims are not submitted directly by the wrongdoers themselves." 155 Cong. Rec. S10854.

II. THE FEDERAL HEALTH PROGRAMS AT ISSUE

23. ***Medicare Part B***. Medicare is a federal program that provides federally subsidized health insurance for persons who are 65 or older or are disabled. *See* 42 U.S.C. §§ 1395 *et seq*. As relevant here, Part B of Medicare provides supplemental benefits to participants to cover DME rentals in addition to physician services and certain prescription drugs. *See generally id*. §§ 1395j–1395w-4.

24. When Medicare beneficiaries receive healthcare coverage under Part B, including for DME rental items like NIVs, they typically are required to cover a portion of the cost in the form of co-pays. Co-pays are intended to give patients an incentive to choose the most cost-effective therapy and, thereby, avoid the billing of unnecessary services.

25. To participate in Medicare Part B, providers – including DME providers like Apria – must execute provider agreements with CMS to establish their eligibility. To be eligible for payment under Medicare Part B, DME providers must certify:

> I agree to abide by the Social Security Act and all applicable Medicare laws, regulations and program instructions that apply to this supplier. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all

applicable conditions of participation in Medicare.

See CMS Form-855S (rev. 05/16) at 24.

26. Further, each time that it submits a Part B claim to Medicare, a DME provider must make a series of certifications regarding the rental item being provided. *See* CMS Form-1500 (rev. 02/12). Those certification include, as relevant here, that the DME provider has "familiarized [itself] with all applicable laws, regulations, and program instructions;" that the claim "complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute [];" and that the items or services being billed "were medically necessary[.]" *Id*. at 2.

27. ***Medicaid***. Medicaid is a joint federal-state program created in 1965 that provides health care benefits for certain groups, primarily the poor and disabled. The federal portion of each state's Medicaid payments, known as the Federal Medical Assistance Percentage ("FMAP"), is based on the state's per capita income compared to the national average. *See* 42 U.S.C. § 1396d(b). Among the states, FMAP is at least 50 percent and as high as 83 percent.

28. The Medicaid programs in all 50 states and the District of Columbia reimburse for DME rentals. The majority of states award contracts to private companies to evaluate and process claims for payment on behalf of Medicaid recipients. Typically, after processing the claims, these private companies then generate funding requests to the state Medicaid programs.

29. Before the beginning of each calendar quarter, each state submits to CMS an estimate of its Medicaid federal funding needs for the quarter. CMS reviews and adjusts the quarterly estimate as necessary, and determines the amount of federal funding each state will be permitted to draw down as it incurs expenditures during the quarter. The state then draws down federal funding as actual provider claims, including claims from DME providers, are presented for payment. After the end of each quarter, the state then submits to CMS a final expenditure

report, which provides the basis for adjustment to the quarterly federal funding amount (to reconcile the estimated expenditures to actual expenditures). *See* 42 C.F.R. § 430.30.

30. Providers who participate in the Medicaid program must sign enrollment agreements with their states that certify compliance with the state and federal Medicaid requirements, including the AKS. Although there are variations among the states, the agreement typically requires the prospective Medicaid provider to agree that he or she will comply with all state and federal laws and Medicaid rules and regulations in billing the state Medicaid program for services or supplies furnished.

31. Furthermore, in many states, Medicaid providers, including DME providers, must affirmatively certify, as a condition of payment of the claims submitted for reimbursement by Medicaid, compliance with applicable federal and state laws and regulations.

32. Many Medicaid service providers are either reimbursed directly by states on a fee-for-service basis, or through claims submitted to Managed Care Organizations ("MCOs"). States contract with MCOs to provide benefits to Medicaid beneficiaries and the MCOs receive monthly capitation payments for providing these services. Providers submit claims for payment to MCOs for services provided to Medicaid beneficiaries enrolled in the managed care plan. Claims for payment submitted to MCOs are deemed to be "claims" under the FCA since the managed care plan is a "contractor, grantee, or other recipient," the money is being used "to advance a Government program or interest," and the Government provides or has provided a portion of the money requested and/or will reimburse the MCO for a portion of the money requested. 31 U.S.C. § 3729(b)(2)(A). In their agreements with providers, MCOs require providers to comply with the rules and regulations of the Medicaid program.

33. ***TRICARE***. The Government, through DOD, administers the TRICARE program. More specifically, TRICARE provides healthcare benefits, including coverage of DME rental

items like NIVs, for certain current and former members of the armed services and their dependents. *See* 10 U.S.C. § 1071 *et seq*.

34. Some TRICARE options require participating members to pay a co-pay and/or to meet a deductible. 32 C.F.R. § 199.4(f). A provider of services generally cannot, as a matter of law, waive these co-pay or deductible requirements. 32 C.F.R. § 199.4(f)(9).

35. Providers of services to TRICARE beneficiaries are required to comply with TRICARE's program requirements, including its anti-abuse provisions. 32 C.F.R. § 199.9(a)(4). TRICARE regulations provide that claims submitted in violation of TRICARE's anti-abuse provisions can be denied. *Id.* § 199.9(b). Kickback arrangements are included within the definition of abusive situations that constitute program fraud. *Id.* §§ 199.2(b), 199.9(c)(12).

36. ***FEHBP***. The Government, through OPM, administers the FEHBP. The FEHBP program provides healthcare benefits, including coverage of DME rental items like NIVs, for certain federal government employees and retirees as well as their family members and survivors. *See* 5 U.S.C. § 8901 *et seq*.

III. THE FEDERAL HEALTH PROGRAMS' MEDICAL NECESSITY REQUIREMENT

37. A fundamental requirement for the Federal health programs' coverage of items or services, including DMEs, is that such items or services are medically necessary.

38. Under Medicare Part B, for example, Congress expressly prohibited, by statute, reimbursement "for any expenses incurred for items or services . . . [that] are not reasonable and necessary for the diagnosis or treatment of illness or injury …" 42 U.S.C. § 1395y(a)(1)(A).

39. In the case of Medicaid, Congress similarly codified the medical necessity requirement by statute by expressly requiring each State Medicaid Plan to "safeguard against unnecessary utilization of [] care and services." 42 U.S.C. § 1395a(30).

40. Pursuant to that statutory mandate, state Medicaid programs have promulgated laws

and regulations to require medical necessity. New York, for example, extends Medicaid coverage only for "medically necessary" treatment, services, and supplies. *See* N.Y. Soc. Serv. L. § 365-a. The Washington Medicaid program likewise expressly conditions payment on whether "the service is medically necessary[.]" *See* WA Admin. Code § 182-502-0100(1)(b).

41. Finally, medical necessity is also a condition of coverage for items or services, including NIV and other DME rentals, under the TRICARE and FEBHP programs. *See*, *e.g.*, 32 C.F.R. § 199.4(a) (TRICARE "will pay for medically or psychologically necessary services and supplies required in the diagnosis and treatment of illness or injury"); 32 C.F.R. § 192(b) (TRICARE coverage of DME is for "medically necessary item[s]").

42. Beyond codifying the medical necessity requirement as a basic condition of payment, the Federal health programs also have provided guidelines and instructions to DME providers like Apria regarding specific aspects of their obligation to comply with this basic requirement. Under Medicare Part B, for example, the CMS contractors that adjudicate DME claims issued program instructions, known as local coverage determinations ("LCDs"), to describe what steps DME providers like Apria need to take to comply with the medical necessity requirement.

43. Specifically, certain LCDs instructed DME providers that they "are responsible for monitoring utilization of DMEPOS [durable medical equipment, prosthetics, orthoticsm and supplies] rental items." Those LCDs further explained, for "ongoing rented DME items" like NIVs, the DME providers not only need to have "information … that justifies the initial provision of the item(s) [], there must be information in the beneficiary's medical record to support that the item continues to remain reasonable and necessary." Finally, those LCDs instructed DME providers that they "must discontinue billing Medicare when rental items or ongoing supply items are no longer being used by the beneficiary."

44. As noted above, *see supra* ¶ 26, DME providers like Apria were required to certify, in connection with submitting each Medicare Part B claim, that they were familiar with "program instructions" like the LCDs and that the claim "complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions[.]" *See* CMS-1500 (02/12) at 2.

IV. THE PROHIBITION AGAINST USING CO-PAY WAIVERS AS AN INDUCEMENT

45. As noted above, the AKS prohibits the offer of remuneration to induce any person to order or lease an item or service covered by programs like Medicare. As early as 1994, the Government made it clear to providers that the AKS's prohibition applies to offers of co-pay waivers for the purpose of inducing Medicare patients to rent or purchase items or services.

46. Specifically, HHS-OIG issued "Special Fraud Alerts" to highlight that if "providers . . . or suppliers forgive financial obligations [such as co-pays] for reasons other than genuine financial hardship of the particular patient, they may be unlawfully inducing that patient to purchase [or rent] items or services from them." 59 Fed. Reg. 65,372, 65,373 (Dec. 19, 1994). As the 1994 Special Fraud Alerts explain, studies "show[] that if patients are required to pay even a small portion of their care, they will be better health care consumers, and select items or services because they are medically needed, rather than simply because they are free." *Id*.

47. Further, while the 1994 Special Fraud Alerts recognized a "hardship exception" to the "prohibition against waiving [co-pays]," it also emphasized that the exception "must not be used routinely," but rather "only occasionally to address the special financial needs of a particular patient." *Id*. at 65,374.

48. In addition, the 1994 Special Fraud Alerts provided a non-exhaustive list of practices that were "indicators" of "improper waivers." *See id*. As relevant here, those include promising beneficiaries that they would not be responsible for the co-pay as well as waiving the co-pay "for a specific group of Medicare patients for reasons unrelated to indigency." *Id*.

49. In 2014, HHS-OIG issued a Special Advisory Bulletin in the context of independent charity patient assistance programs that further highlighted how limiting co-pay assistance to "a subset of available products," especially "only for expensive [products]," can raise AKS concerns. *See* 79 Fed. Reg. 31,120, 31,222 (May 30, 2014). This is because, as the Special Advisory Bulletin explains, limiting co-pay assistance "to expensive products may steer patients in a manner that is costly to Federal health care programs" and also "may steer patients away from potentially more beneficial products because assistance is available for one treatment and not another." *Id*.

FACTUAL ALLEGATIONS

A. NIV Treatment and the Federal Health Programs' Coverage for NIV Rentals

50. NIVs are a type of complex respiratory equipment designed to treat patients with chronic respiratory failure.

51. By way of comparison, patients with a respiratory condition typically can receive at-home treatment using four types of respiratory equipment and/or supplies. Those are – in increasing order of the complexity of the treatment and the cost of the equipment – *i*) at home oxygen equipment and supplies; *ii*) constant pressure support ("CPAP") devices; *iii*) bi-level pressure support ("BiPAP") devices; and *iv*) NIVs.

52. As relevant here, NIVs differ from CPAP and BiPAP devices in that, instead of delivering air at one or two specific air pressure settings, NIVs can dynamically adjust the pressure levels of the air flow they deliver with each breath. The ability to adjust the air flow pressure level dynamically allows NIVs to, among other things, ensure that patients with constricted airways can nonetheless achieve the tidal volume prescribed by their physicians.

53. Due to the nature of NIV treatment as well as the nature of the respiratory condition that NIVs are used to treat, it is generally understood, including by Apria, that patients need to

use NIVs regularly in order to get the benefit of NIV treatment.

54. Further, Federal health programs reimburse NIV rentals differently from CPAP and BiPAP devices. Medicare Part B, for example, reimburses NIV rentals using a different billing code and at a much higher rate than CPAP or BiPAP device rentals. During the relevant period, CMS used the billing codes E0466 and E0467 for NIV rentals and the billing codes E0601 and E0470 for CPAP and BiPAP rentals. Medicare's reimbursement rate for an NIV rental was as high as $1,400 per month, whereas the monthly rates for CPAP and BiPAP rentals were approximately $100 and $300, respectively.

55. In addition, CMS also classified NIVs in the "frequent and substantial servicing" category for purposes of Medicare Part B coverage, whereas CPAP and BiPAP devices were classified as "capped rental" items. Due to this difference, a DME provider like Apria could bill Medicare for an NIV rental for the machine's full service life – typically five years – instead of being limited to only billing for up to 13 months as is the case of a "capped" CPAP or BiPAP rental.[2]

B. Apria's Intense Focus on Increasing NIV Rental Revenue

56. In or about April 2014, as part of an internal strategic review, Apria's senior executives began discussing whether to make the then-nascent NIV rental business a high priority for Apria. In the course of those discussions, Apria executives recognized that Medicare Part B's high reimbursement rate for NIVs meant that prioritizing NIV rentals would provide Apria with a way to quickly improve its revenue, profit, and cash position.

57. In or about August 2014, senior executives at Apria decided to make the expansion of the NIV rental business a top priority for the company. Specifically, they established a goal

[2] After 13 months, Medicare would deem the CPAP or BiPAP device as having been purchased by the patient and would stop reimbursing a DME provider for the item even if the patient continued to use the CPAP or BiPAP device supplied by the provider.

for Apria to increase its NIV rental revenue from $5 million in 2014 to $30 million in 2015.

58. To achieve that aggressive growth goal, Apria's executives and managers implemented a variety of sales and operational practices. As relevant here, Apria created an NIV-specific marketing program that emphasized Apria's "clinical commitment" to have the RTs at its branches conduct regular visits to assess NIV patients' conditions and whether they complied with the treatment protocol prescribed by their physicians.

59. Apria's senior executives also directed regional and branch office managers to institute targets for NIV orders and "starts" (new patients beginning service on an NIV) for individual salespeople. Salespeople who generated large numbers of NIV starts received tens of thousands of dollars in annual bonuses, whereas salespeople who failed to meet the NIV targets were at risk for termination.

60. Further, to maximize the number of NIV rentals, Apria implemented a series of "NIV patient mining" programs. Those programs involved Apria's branch office sales and clinical staff combing through medical records for existing oxygen and BiPAP patients to find patients that salespeople could try to place on NIVs.

61. Finally, as discussed below, *see infra* ¶¶ 79–81, Apria made extensive changes to its co-pay policy starting in late 2014 so that it could offer co-pay waivers more frequently to NIV patients as compared to patients with less expensive, and less profitable, rental items like CPAP devices or oxygen machines.

C. Apria Routinely Ignored the Continued Use Aspect of the Medical Necessity Requirement When It Submitted NIV Claims to the Federal Health Programs

62. During the relevant period, Apria understood that to comply with the continued use aspect of the Federal health programs' medical necessity requirement, it had an obligation to periodically verify that the program beneficiaries with NIV rentals were continuing to use their NIVs as well as to stop billing the programs if beneficiaries stopped using their NIVs.

63. For example, according to an internal guideline known as "Reimbursement Update 470" ("RU-470"), which was in effect from 2013 to 2017, "Apria is responsible for monitoring the utilization of DME[] rental items." RU-470 further stated that "Medicare requires that providers discontinue billing when rental items [] are no longer being used by the beneficiary."

64. Apria's compliance staff also understood that Federal health programs required DME providers like Apria to maintain records showing that beneficiaries with NIV rentals continued to utilize their NIVs and to need NIV treatment.

65. For example, in February 2016, an Apria compliance manager asked a branch manager in Missouri to obtain documentation to show that an NIV patient is "continuing to use/need the NIV therapy." According to the compliance manager, such documentation was needed because "Medicare should not be billed if the patient is not using the device." Similarly, in a May 2016 e-mail exchange, another compliance manager at Apria asked a branch manager in New York to "obtain documentation … showing continued medical need for the NIV therapy and that the patient is benefitting from the therapy" in response to a Medicare audit.

66. In practice, however, Apria routinely failed to ensure that the NIV rental claims it was submitting to Federal health programs were for NIVs that patients continued to need and use. While Apria relied on RTs at its branch offices to monitor patients' NIV usage and made the RT visits a core component of its marketing strategy, Apria did not hire a sufficient number of RTs to make the necessary number of visits to NIV patients. Instead, through a series of cost-cutting measures between 2015 and 2017, Apria repeatedly reduced the number of RTs at its branch offices.

67. As a result, Apria's RTs frequently did not make home visits to verify patient's NIV usage and their ongoing need for the equipment.

68. The issue of missed RT visits was also widely recognized within Apria. As early as

December 2015, site visits to branch offices by corporate executives and reports from branch and regional managers showed that a significant number of RT visits to NIV patients were not being conducted. For example, an internal analysis showed that in December 2016, Apria's RTs failed to complete more than half of the visits to NIV patients mandated by Apria's NIV clinical procedures within all three of Apria's operational zones.

69. In July 2017, moreover, the vice president heading Apria's NIV program at Apria warned one of the company's senior executives that as many as 50% of the RT home visits that needed to be done as part of Apria's baseline clinical policy were not being made and those missed RT visits were undermining the "clinical foundation" of the NIV program. Despite that warning, Apria implemented another reduction of its RT staff in late 2017.

70. As result of the missed RT visits, Apria frequently lacked data or information regarding whether many of its NIV patients – including Federal health program beneficiaries – were continuing to use their NIVs or had stopped using the machines. Yet, Apria kept billing the programs on a monthly basis for these NIVs, often well after the patients stopped using them. For example:

- Patient A, a Medicare beneficiary living in Brooklyn, NY, received an NIV rental from Apria in January 2018 after her discharge from a rehabilitation facility. Patient A used the device sporadically between January and April 2018. Starting in or about May 2018, however, Patient A stopped using her NIV because she felt very uncomfortable whenever she used the device. Patient A's daughter put the NIV in a grocery box inside a living room closet, where it remained until at least December 2018. Apria's RTs did not visit Patient A after May 2018 to verify that she continued to use her NIV. During this period, Apria submitted numerous claims to Medicare and received thousands of dollars in reimbursements for this NIV rental.
- Patient B, a Medicare beneficiary who lived in the Denver area, received an NIV rental from Apria in October 2014. Between January 2015 and March 2017, Apria's RTs did not visit Patient B to verify that she was continuing to use the machine. If Apria's RTs had visited during that period, they would have known

that Patient B had stopped using her NIV. During this period, Apria submitted more than 20 claims to Medicare and received thousands of dollars in reimbursements for this NIV rental.

- Patient C, a Medicaid beneficiary living in the Bronx, NY, received an NIV rental from Apria in August 2016. Between August 2016 and August 2018, Apria's RTs did not visit Patient C to verify that she was continuing to use the machine. If Apria's RTs had visited Patient C during that period, they would have learned that she had not been using her NIV. Apria submitted numerous claims to Medicaid for this NIV rental and sought thousands of dollars in payment.

71. In addition, Apria did not adequately train its branch office and billing staff on the need to stop billing Federal health programs when the company learned that patients were no longer using their NIVs.

72. When Apria's RTs were able to visit NIV patients, they found in many cases that patients had stopped using their NIVs for various reasons, such as an inability to adjust to the treatment. Although Apria's reimbursement guidelines mandated that billing should be "discontinued" in such cases, the branch office employees and billing staff at Apria often did not take steps to stop seeking payments from Federal health programs or to determine if the NIV rentals were still medically necessary.

73. Apria frequently continued to bill the Federal health programs even after it had information indicating that program beneficiaries had stopped using their NIVs. For example:

- In the case of Patient B, Apria RTs downloaded the usage data from this patient's NIV in October 2017 and January 2018. The data showed that Patient B was not using her NIV. Apria, however, did not promptly discontinue billing Medicare; instead, Apria submitted approximately 10 claims to Medicare between October 2017 and August 2018 and received thousands of dollars in reimbursements for this NIV rental.
- Patient D, a Medicare/Medicaid dual-eligible beneficiary in the Chicago area, received an NIV rental from Apria in April 2016. RT visit records show that Apria was aware that Patient D stopped using her NIV after July 2016. However, instead of promptly discontinuing to bill Medicare and Medicaid, Apria submitted

more than 20 claims to those programs between July 2016 and June 2019 and received thousands of dollars in reimbursements for this NIV rental.

- Patient E, a Medicare/Medicaid dual-eligible beneficiary living in the Dallas-Fort Worth area, received an NIV rental from Apria in March 2017. RT visit records reveal that Apria was aware that Patient E stopped using her NIV after July 2017. Rather than discontinue billing Medicare and Medicaid once it discovered that Patient E was no longer using her NIV, Apria submitted at least a dozen claims between August 2017 and August 2018 and received thousands of dollars in reimbursements for this NIV rental.

D. Apria Rented Astral NIVs to Federal Program Beneficiaries for Use in the PAC Mode in Contravention of the Medical Necessity Requirement

74. As noted above, *see supra* ¶ 52, NIVs are functionally different from CPAP and BiPAP devices because they can dynamically adjust the pressure level of the air flow, whereas CPAP and BiPAP devices deliver air at one or two specific air pressure levels.

75. Federal health programs like Medicare have differentiated between the manner in which payments are made for NIVs and for devices used to provide CPAP or BiPAP therapy. For example, in 2006, CMS publicly explained that respiratory devices used to provide "bi-level pressure capability" were "excluded from the FSS [frequent and substantial servicing] payment category," which is the category for the NIV billing codes. *See* 71 Fed. Reg. 4,518, 4,522 (2006). Further, LCDs issued by Medicare contractors expressly instructed DME providers that even if an NIV "may have the capability of operating in a bi-level [pressure support] mode," it would nonetheless be considered "not reasonable and necessary" for a DME provider to submit claims for NIVs being "used to provide CPAP or [BiPAP] therapy." *See* LCD L33800 (eff. 10/2015). Finally, CMS manuals stated more generally that as a facet of the medical necessity requirement, Medicare would not provide full reimbursement "when the type of equipment furnished substantially exceeds that required for the treatment of the illness [] involved." *See* Medicare Benefits Policy Manual Chapter 15 § 110.1C.

76. Apria, in turn, understood this facet of the medical necessity requirement. Specifically, as an Apria compliance manager acknowledged under oath, the company was aware that it would not be appropriate to bill Medicare using the NIV code for an NIV machine that was being set up for use solely in the BiPAP setting.

77. During the relevant period, Apria offered a type of BiPAP device, the VPAP S9 from ResMed, that was covered by Medicare as a capped rental item at the BiPAP rate (*i.e.*, approximately $300 per month), which was far less than the Medicare rate for NIVs (*i.e.,* approximately $1,400 per month).

78. The VPAP S9 provided, among other therapy settings, a BiPAP setting called PAC mode. During the relevant period, PAC mode was also available as one of the therapy settings on the Astral NIV, one of the NIVs offered by Apria. As internal emails show, Apria's NIV clinical team recognized in 2015 that PAC mode on the Astral NIV was a type of bi-level therapy.

79. Nonetheless, Apria executives encouraged Apria's sales staff to actively urge physicians to order the costly Astral NIVs for use in the PAC mode setting. Further, when they urged physicians to order the Astral NIVs in PAC mode, Apria's salespeople frequently did not tell the physicians that PAC mode was also available through the VPAP S9, at a lower cost.

80. On a number of occasions, this sales strategy resulted in Apria renting the more expensive Astral NIVs to patients with orders for PAC mode therapy, including patients covered by Federal health programs, even though the less expensive VPAP S9 rentals would have met those patients' medical needs.[3] For example:

- Patient F, a Medicare beneficiary from the Chicago area, received an Astral NIV rental from Apria in December 2015, which was set to PAC mode. Despite

[3] While the Astral NIV had several features that were not available on the VPAP S9, the Astral orders in question typically did not prescribe that patients use such features.

knowing that Patient F did not medically require an Astral NIV and that a much less costly device would have provided the same type of therapy and adequately met the patient's needs, Apria submitted numerous claims to Medicare using the NIV billing codes and received thousands of dollars in reimbursements for this rental.

- Patient G, a Medicare beneficiary in the Miami-Fort Lauderdale area, received an Astral NIV rental in March 2016, which Apria set in PAC mode. Despite knowing that Patient F did not medically require an Astral NIV and that a much less costly device would have provided the same type of therapy and adequately met the patient's needs, Apria submitted a dozen claims to Medicare between March 2016 and May 2017 using the NIV billing codes and received thousands of dollars in reimbursements for this rental.

E. Apria Offered Co-Pay Waivers to Induce Medicare and TRICARE Beneficiaries to Rent NIVs from Apria

81. In late 2014, shortly after Apria decided to prioritize the growth of its NIV business, managers and executives at Apria became aware that some patients decided not to rent NIVs due to the large co-pays (typically 20% of the monthly Medicare reimbursement rate) required by Medicare and other payors for NIV rentals.

82. In response, managers at a number of Apria's branches directed salespeople at those branches to routinely discuss the availability of co-pay waivers with NIV patients, including before the patients raised concerns about their ability to make these payments. In a number of cases, the branch managers also authorized salespeople to offer co-pay waivers to persuade patients to rent NIVs from Apria instead of other DME suppliers.

83. Further, senior executives at Apria decided to make a series of revisions to Apria's co-pay policy, including to limit the availability of co-pay waivers only to patients whose monthly co-pay exceeded $100 and to waive 100% of the co-pay as long as a patient's income was less than four times the federal poverty level.

84. Apria executives picked the $100 monthly co-pay threshold because they wanted Apria to offer co-pay waivers primarily to NIV patients instead of patients who rented cheaper

items like CPAP devices or oxygen supplies from Apria. At the same time, Apria altered its practice so that it no longer waived co-pays for patients with less expensive rental items even if they indicated that they had genuine financial needs for the waivers.

85. Apria executives and managers recognized that offering more co-pay waivers for NIV patients was necessary to influence patients to accept the NIV rentals. Indeed, Apria amended its co-pay policy in early 2015 to allow a select group of executives to approve "exception" co-pay waivers for patients who did not otherwise qualify. While Apria's co-pay policy stipulated that such "exception" waivers may be given only to patients whose monthly co-pay exceeded $200, Apria executives repeatedly approved "exception" waivers for patients whose monthly co-pay were under $200. In a number of such cases, the internal e-mails show that a main factor Apria executives relied on to approve "exception" waivers was how much Medicare or other payors would reimburse Apria for the NIV rentals.

86. In addition, by waiving 100% of the co-pay whenever a patient's income was less than four times the federal poverty level, Apria gave full co-pay waivers to a large number of NIV patients without assessing whether those patients could have afforded some portion of their co-pay responsibilities.

87. By regularly offering and giving co-pay waivers to Medicare and TRICARE beneficiaries, Apria also induced a number of beneficiaries to rent or continue to rent the NIVs that were not medically necessary.

* * *

88. As result of the above-referenced improper practices, Apria submitted thousands of false claims to the Federal health programs in violation of the FCA and improperly obtained millions of dollars in payments.

FIRST CLAIM

Violations of the False Claims Act: Presenting False Claims for Payment

(31 U.S.C. § 3729(a)(1)(A)

89. The Government incorporates by reference paragraphs 1 through 88 above as if fully set forth in this paragraph.

90. The Government asserts claims against Apria under Section 3729(a)(1)(A) of the FCA, 31 U.S.C. § 3729(a)(1)(A).

91. As a result of its improper practices set forth above in connection with the rental of NIVs to Federal health program beneficiaries — including its disregard of the continued use and appropriate therapy aspects of the medical necessity requirement and its use of co-pay waivers as an inducement — Apria knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1)(A).

92. If the Federal health programs had been fully aware of Apria's improper practices alleged above, those programs would not have reimbursed Apria's NIV rental claims.

93. By reason of the false or fraudulent NIV rental claims that Apria knowingly presented, or caused to be presented, for payment or approval, the Government has been damaged in a substantial amount to be determined at trial, and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

SECOND CLAIM

Violations of the False Claims Act: Use of False Statements

(31 U.S.C. § 3729(a)(1)(B))

94. The Government incorporates by reference paragraphs 1 through 88 above as if fully set forth in this paragraph.

95. The Government asserts claims against Apria under Section 3729(a)(1)(B) of the FCA, 31 U.S.C. § 3729(a)(1)(B).

96. As a result of its improper practices set forth above in connection with the rental of NIVs to Federal health program beneficiaries — including its disregard of the continued use and appropriate therapy aspects of the medical necessity requirement and its use of co-pay waivers as an inducement — Apria made, used, or caused to be made or used, false records or statements that were material to getting false or fraudulent claims paid by the Federal health programs in violation of 31 U.S.C. § 3729(a)(1)(B).

97. If the Federal health programs had been fully aware of the falsity of the records or statements that Apria made, used, or caused to be made or used, those programs would not have reimbursed Apria's NIV rental claims.

98. By reason of the false records or statements that Apria made, used, or caused to be made or used in connection with getting false or fraudulent claims paid by the Federal health programs, the Government has been damaged in a substantial amount to be determined at trial, and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

PRAYER FOR RELIEF

WHEREFORE, plaintiff, the Government, respectfully requests that judgment be entered in its favor as follows:

(a) on the First and Second Claims for relief, a judgment for treble the Government's damages, in an amount to be determined at trial, plus a civil penalty in the maximum applicable amount for each violation of the FCA;

(b) an award of costs incurred by the Government pursuant to 31 U.S.C. § 3729(a)(3); and

(c) such further relief as is proper.

Dated: New York, New York
December 15, 2020

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