CAUSE NO. _____

THE STATE OF TEXAS *ex rel.* HEALTH CHOICE ALLIANCE, LLC *Plaintiffs*, v. ELI LILLY & COMPANY, INC. *Defendant*.	§ § § § § § § § § § § § § § §	IN THE DISTRICT COURT 71ST JUDICIAL DISTRICT HARRISON COUNTY, TEXAS

The State of Texas and Relator Health Choice Alliance, LLC ("Relator" or "HCA") bring this civil law enforcement action pursuant to the Texas Health Care Program Fraud Prevention Act ("THFPA"), Tex. Hum. Res. Code § 36.001, *et seq*.

PRELIMINARY STATEMENT

1. Defendant Eli Lilly & Company, Inc. ("Lilly") is one of the largest pharmaceutical companies in the world. It manufactures and markets medicines that have been approved by the Federal Drug Administration ("FDA") to treat numerous chronic diseases, including of relevance here products (collectively, the "Covered Drugs") that treat diabetes, osteoporosis, migraines, obesity, auto-immune disorders, and multiple types of cancer.

2. Because many of the Covered Drugs compete in a marketplace saturated with medications that deliver—or claim to deliver—similar therapeutic results, Lilly needed a compelling promotional strategy to support them. Lilly thus devised two programs aimed at incentivizing Providers[1] to prescribe and continue to prescribe the Covered Drugs over alternatives.

3. In the first scheme (the "Free Nurse Program"), Lilly provided (and/or had assistance from third parties providing) in-kind remuneration to Providers in the form of free patient-care services to induce Providers to recommend or prescribe the Covered Drugs to their patients.

4. In the second scheme (the "Support Services Program"), Lilly provided (and/or had assistance from third parties providing) in-kind remuneration to Providers in the form of reimbursement support services.

[1] As used herein, the term "Provider" refers to any physician or Advanced Practice Provider authorized to write prescriptions, as well as their employers.

5. By inducing Providers to prescribe and/or continue to prescribe the Covered Drugs in violation of Texas law, Lilly committed, and continues to commit, a number of unlawful acts in violation of the THFPA.

6. This case is not about whether the Covered Drugs are effective—it is about whether Lilly violated Texas law by providing remuneration or items of value to induce Providers to prescribe the Covered Drugs over other drugs on the market.

DISCOVERY CONTROL PLAN

7. Plaintiffs intend to conduct discovery in this case under a Level 3 Discovery Control Plan, pursuant to Rule 190.4 of the Texas Rules of Civil Procedure.

STATEMENT OF RELIEF

8. Plaintiffs seek monetary relief over $1,000,000. Tex. R. Civ. P. 47(c)(4).

THE PARTIES

9. Plaintiffs are the State of Texas, by and through the Attorney General of Texas, Ken Paxton, and Relator, Health Choice Alliance, LLC, a New Jersey-based entity organized under the laws of the State of Delaware (collectively, Plaintiffs).

10. Defendant Lilly makes, markets, and sells pharmaceuticals, including the Covered Drugs, throughout the United States and including in Texas. Lilly is organized under the laws of the State of Indiana and is headquartered in Indianapolis, Indiana.

THE COVERED DRUGS

11. Lilly's unlawful conduct detailed herein includes at the very least the following products/Covered Drugs:

- Alimta, an injectable medication that was approved by the FDA for the treatment of metastatic non-squamous non-small cell lung cancer;

- Basaglar, an injectable medication that was approved by the FDA for the treatment of type 1 diabetes;

- Ebglyss, an injectable medication that was approved by the FDA for the treatment of moderate-to-severe eczema that is not controlled with topical therapies;

- Emgality, an injectable medication that was approved by the FDA for the treatment of migraines;

- Forteo, an injectable medication that was approved by the FDA for the treatment of osteoporosis in certain patient populations;

- Humalog/Insulin Lispro/Lyumjev, an injectable medication that was approved by the FDA for the treatment of type 1 and type 2 diabetes;

- Humulin, an injectable medication that was approved by the FDA to manage blood sugar levels in people with diabetes mellitus;

- Jaypirca, an orally-administered medication that was approved by the FDA for the treatment of chronic lymphocytic leukemia and small lymphocytic lymphoma in adults who have already received at least two types of therapy;

- Mounjaro, an injectable medication that was approved by the FDA to treat type 2 diabetes and for weight management in adults;

- Retevmo, an orally-administered medication that was approved by the FDA for the treatment of certain cancers whose tumors contain specific changes in a gene called *RET*;

- Rezvoglar, an injectable medication that was approved by the FDA for the improvement of glycemic control in adult and pediatric patients with diabetes mellitus;

- Taltz, an injectable medication that was approved by the FDA for the treatment of several inflammatory conditions;

- Verzenio, an orally-administered medication that was approved by the FDA for the treatment of certain types of breast cancer; and

- Zepbound, an injectable medication that was approved by the FDA for the treatment of obesity and obstructive sleep apnea.

JURISDICTION AND VENUE

12. This Court has subject-matter jurisdiction over this action pursuant to the THFPA, which provides statutory remedies to redress Lilly's violations of Tex. Hum. Res. Code § 36.002. *See* Tex. Hum. Res. Code § 36.052. The THFPA provides authority for this action to be brought

by Relator and on behalf of the State of Texas. Tex. Hum. Res. Code § 36.101.

13. This Court has jurisdiction over Lilly because it does business in the State of Texas and committed the unlawful acts alleged in this Petition in whole or in part in Texas.

14. Jurisdiction is further proper because the amount sought from Lilly is in excess of the minimum jurisdictional limits of this Court.

15. Upon information and belief, venue is proper in Harrison County pursuant to the THFPA. Tex. Hum. Res. Code § 36.052(d). A lawsuit filed under the THFPA "shall be brought in Travis County or in a county in which any part of the unlawful act occurred." *Id.*

16. Upon information and belief, venue is proper in Harrison County because Lilly's unlawful acts occurred, in part, in Harrison County. Among other things, Lilly actively promotes the Covered Drugs in Harrison County using the Free Nurse and Support Services programs, and regularly solicits Providers to enroll their patients in these programs.

17. For example, earlier this year, Lilly sales rep Janette Boorman, offered at least one Harrison County-based Provider reimbursement support services for two Covered Drugs (Mounjaro and Zepbound).

STATUTORY BACKGROUND

18. In relevant part, Tex. Hum. Res. Code § 36.052(a)(1)-(a)(4) establishes civil penalties for each unlawful act committed by Lilly and three times the value of payment(s) made and/or benefit(s) provided under the Medicaid program as a result of its unlawful acts.

19. Texas Medicaid is a jointly funded state-federal health care program administered by the Texas Health and Human Services Commission. Texas uses Medicaid to improve the health and wellness of people who might otherwise not be able to obtain medical care. Medicaid makes payments directly to health care Providers and/or managed-care organizations, and not directly to

individuals seeking a prescription.

20. Relevant here, section 36.002(13) of the THFPA provides that a person commits an unlawful act if the person "knowingly engages in conduct that constitutes a violation under Section 32.039(b)."

29. The Texas Anti-Kickback Statute, codified under section 32.039(b) of the Texas Human Resources Code and incorporated into the THFPA by section 36.002(13), provides that a person commits a violation if the person:

> (b)(1-e) offers or pays, directly or indirectly, overtly or covertly any remuneration, including any kickback, bribe, or rebate, in cash or in kind to induce a person to purchase, lease, or order, or arrange for or recommend the purchase, lease or order of, any good, facility, service, or item for which payment may be made, in whole or in part, under the medical assistance program;
>
> (b)(1-f) provides, offers, or receives an inducement in a manner or for a purpose not otherwise prohibited by this section or Section 102.001, Occupations Code, to or from a person, including a recipient, provider, employee or agent of a provider, third-party vendor, or public servant, for the purpose of influencing or being influenced in a decision regarding:
>
> > (A) selection of a provider or receipt of a good or service under the medical assistance program;
> >
> > (B) the use of goods or services provided under the medical assistance program; or
> >
> > (C) the inclusion or exclusion of goods or services available under the medical assistance program.

21. Texas enacted the THFPA to recover and prevent fraud and unlawful acts that affect the Medicaid program. Accordingly, violations of § 32.039(b), are expressly incorporated under the THFPA § 36.002(13) as an unlawful act.

22. Within the meaning of the Texas Human Resources Code, "knowingly" is defined to include reckless disregard and conscious indifference. Tex. Hum. Res. Code § 36.0011(a)(2)-(3). Further, proof of "specific intent to commit an unlawful act under Section 36.002 is not

required" to show a person "acted 'knowingly' with respect to information under this chapter." Tex. Hum. Res. Code § 36.0011(b).

23. Remuneration, for purposes of Texas law, includes the transfer of anything of value, whether cash or in-kind consideration, directly or indirectly, covertly or overtly. Importantly, the statute has been consistently interpreted broadly to cover any arrangement where one purpose of the remuneration is to obtain money for referral of services or to induce further referrals. This includes any "service" that would eliminate an expense the physician would have otherwise incurred or any "service" that is sold to a physician at less than fair market value. "Inducement" is defined to include a service, cash in any amount, entertainment, or any item of value. Tex. Hum. Res. Code § 32.039(a)(1-a).

24. Anti-kickback provisions are designed to, among other things, ensure that patient care will not be improperly influenced by inappropriate compensation from the pharmaceutical industry, and that healthcare professionals remain free of conflicts of interest that could impact treatment decisions.

25. To participate in Texas Medicaid, Providers and suppliers certify compliance with Texas law prohibiting kickbacks and fraud.

BACKGROUND AND FACTS

LILLY'S SCHEMES AFFECTED THE TEXAS MEDICAID PROGRAM

26. Generally, when a Provider prescribes one of the Covered Drugs, a patient is provided with a prescription that is then filled at a pharmacy. The pharmacy then submits the claim for payment to Texas Medicaid for reimbursement.

Medicaid

27. Medicaid is a joint federal-state program created in 1965 that provides health care

benefits for certain groups, primarily the poor and disabled. Each state, including Texas, administers a State Medicaid program.

28. The federal Medicaid statute requires each participating state to implement a plan containing certain specified minimum criteria for coverage and payment of claims. 42 U.S.C. §§ 1396, 1396a(a)(13), 1396a(a)(30)(A). While drug coverage is an optional benefit, the Medicaid programs of all states provide reimbursement for prescription drugs.

29. 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. 42 U.S.C. § 1396d(b). Federal funding under Medicaid is provided only when there is a corresponding state expenditure for a covered Medicaid service to a Medicaid recipient. The federal government pays to the state the statutorily established share of the "total amount expended . . . as medical assistance under the State plan." 42 U.S.C. § 1396b(a)(l).

30. The vast 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 generate funding requests to the state Medicaid programs.

31. Before the beginning of each calendar quarter, each state submits to the Center for Medicare and Medicaid Services ("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 pharmacies seeking payment for drugs, are presented for payment. After the end of each quarter, the state 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). 42 C.F.R. § 430.30.

32. Claims tainted by illegal kickbacks—including the mere offer of a kickback—are not authorized to be paid under state regulatory regimes. In fact, Providers who participate in the Medicaid program must sign enrollment agreements with their states that certify compliance with the state and federal Medicaid requirements. 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 regulations in billing the state Medicaid program for services or supplies furnished.

33. Furthermore, in many states, including Texas, Medicaid Providers, including both physicians and pharmacies, must affirmatively certify compliance with applicable federal and state laws and regulations.

34. In Texas, "[P]roviders (and submitters on behalf of providers) must affirm that they have read, understood, and agree to the certification and terms and conditions of the prior authorization request" before submitting each prior authorization request. By agreeing, the provider and authorization request submitter certify that the information supplied concerning the prior authorization "constitute true, correct, and complete information." Further, the provider and authorization request submitter "understand that payment of claims related to this prior authorization will be from federal and state funds, and that falsifying entries, concealment of a material fact, or pertinent omissions may constitute fraud and may be prosecuted under applicable federal and/or state law." The consequences of omitting information or failing to provide true and accurate information include "termination of the provider's Medicaid enrollment and/or personal

exclusion from Texas Medicaid."[2]

35. Additionally, "Texas Medicaid service providers are required to certify compliance with or agree to various provisions of state and federal laws and regulations."[3]

LILLY PARTICIPATED IN TWO UNLAWFUL SCHEMES TO INDUCE AND INFLUENCE PROVIDERS TO PRESCRIBE THE COVERED DRUGS

Background

36. The diseases the Covered Drugs are approved to treat are all chronic, life-long diseases. As such, drugs that treat these life-long diseases, like the Covered Drugs, are oftentimes life-long drugs. What's more, once a patient is prescribed a particular treatment, there is potential for life-long sales. As such, drug manufacturers compete fiercely to gain access to Providers and persuade them to prescribe their products over those of competitors.

37. Motivated by profit, Lilly devised the two schemes.

Scheme One: Lilly Provides In-Kind Remuneration to Providers in the Form of Free Nursing Services

38. In the first scheme, Lilly, with assistance from third parties, provided and continues to provide the services of free nursing staff, in part to induce and influence Providers to recommend the Covered Drugs to their patients.

39. Medical care for chronically ill patients does not stop after the diagnosis is made and a treatment regimen is selected. The relevant literature recognizes that Providers have a "duty

[2] Texas Medicaid Provider Procedures Manual §§ 5.5.1.2.1 – 5.5.1.2.3 (July 2024), *available at* http://www.tmhp.com/Pages/Medicaid/Medicaid_Publications_Provider_manual.aspx.

[3] Texas Medicaid Provider Procedures Manual § 1.7.9 (July 2024) (emphasis in original), *available at* http://www.tmhp.com/Pages/Medicaid/Medicaid_Publications_Provider_manual.aspx.

to attend" to the patient throughout the course of treatment.[4] Thus, the Provider has an ongoing duty to the patient that continues throughout the course of treatment. This duty requires the Provider or his or her staff to consistently monitor the patient's response to medication, treatment, and vitality—a task that typically involves multiple telephone calls, office visits, and communication with the patient.

40. While the treatment of chronic diseases requires Providers' continuous involvement post-diagnosis and the constant monitoring of the patients' reaction to and tolerance for treatment, following-up and monitoring patients are not profitable endeavors for Providers.

41. Much of the required follow-up and monitoring work requires telephonic interactions. But Providers are severely limited in the manner in which they can bill government-sponsored programs like Medicare or Medicaid for this type of follow-up work.

42. For instance, Providers are only allowed to bill for "brief communication technology-based services, e.g., virtual check-in[s]" where the patient they are seeing is "an established patient" and the telephonic or virtual interaction is "not originating from a related e/m service provided within the previous 7 days nor leading to an e/m service or procedure within the

[4] *See, e.g.*, T. Thirumoorthy, *The Professional Duties of the Doctor in the Role of a Healer*, SMA News, Aug. 2012, at 22 ("The doctor should continue to serve the patient and provide appropriate access to care in a timely manner. The doctor has an ethical and legal duty to attend as required by his patient's needs and should not delegate critical duties to juniors. If a doctor delegates duties to another clinician, he must ensure that the attending clinician is adequately informed and competent. The doctor should never abandon his patient . . ."); AMA Code of Medical Ethics Opinion § 1.1.3(b) ("Physicians can best contribute to a mutually respectful alliance with patients by serving as their patients' advocates and by respecting patients' rights. These include the right . . . [t]o receive information from their physicians and to have opportunity to discuss the benefits, risks, and costs of appropriate treatment alternatives, including the risks, benefits and costs of forgoing treatment. Patients should be able to expect that their physicians will provide guidance about what they consider the optimal course of action for the patient based on the physician's objective professional judgment.").

next 24 hours or soonest available appointment."[5] As a result, as market commentators have noted, "doctors' offices are struggling to man the phones: handling everything from appointment and prescription refill requests, to concerns from sick patients, to billing issues. But insurance carriers don't pay doctors for any of those phone calls, which doctors estimate cost $15 to $20 each. Now, more offices and hospitals are looking for ways to take fewer patients' calls."[6]

43. And even in instances when the patients are able to travel to the Providers' offices for in-person follow-up, Government-sponsored plans usually pay a reduced rate for care administered by the Providers' staff.[7] Full rates are paid for staff's services only if the Providers are "present in the office suite and immediately available to provide assistance and direction throughout the time the aide is performing services."[8]

44. Seeking to capitalize on the fact that follow-up and patient monitoring work is unprofitable for Providers, Lilly devised the Free Nurse Program.

45. Specifically, upon receiving FDA approval for certain of the Covered Drugs,[9]

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[5] https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet.

[6] *See* J. Wieczner, *The Doctor Won't Take Your Call: Physicians Hate Phone Calls, and Not Just Because They Can't Bill You*, MarketWatch, July 16, 2013, *available at* www.marketwatch.com/story/the-doctor-wont-take-your-call-2013-07-16; *see also Coding for Telephone Consultations*, Tex. Med. Ass'n, Mar. 23, 2010, *available at* https://www.texmed.org/template.aspx?id=5422 (noting that "Medicare does not reimburse" for, among other things, "telephone evaluation and management (E&M) service provided by a physician to an established patient, parent, or guardian not originating from a related E&M service or procedure within the next 24 hours or soonest available appointment").

[7] *See* G. John Verhovshek, *The Basics of Incident-to Billing*, Physicians Practice, Nov. 16, 2021, *available at* https://www.physicianspractice.com/view/the-basics-of-incident-to-billing.

[8] *See id.*

[9] The Covered Drugs for which the Free Nurse Program has been available include, at the very least: Basaglar, Ebglyss, Emgality, Forteo, Humalog/Insulin Lispro/Lyumjev, Humulin, Rezvoglar, Taltz, and Verzenio.

Lilly began offering and providing Providers the time, service and expertise of nursing staff and other individuals who were trained to offer patient support to help manage these Providers' patients and engage directly with patients to ensure that they were looked after—without burdening the prescribing Providers.

46. Lilly touts certain aspects of the Free Nurse Program in product brochures.

47. For example, the website Lilly maintains for Ebglyss touts the availability of "one-on-one injection training with a registered nurse."

48. Similarly, the website Lilly maintains for Taltz touts the availability of "Injection Training" administered "free of charge to patients and caregivers" in "either in-person or [by] telephone" and the availability of "ongoing support" as a "personal patient resource to help answer questions or concerns."

49. In addition, through a web portal called LillyDirect that offers to connect patients with "independent telehealth services" for "in-person" care. While the LillyDirect portal purports to connect patients with providers who are independent from Lilly, it is yet another tool Lilly uses to funnel patients to certain of the Covered Drugs.[10]

50. The availability of the Free Nurse Program is a key part of Lilly's strategy for certain Covered Drugs, and was particularly effective around the time when these products were launched and Lilly was attempting to persuade Providers to begin writing prescriptions for Lilly's products.

51. Because it acts to induce Providers to prescribe the Covered Drugs, Lilly's Free

[10] The LillyDirect portal services at least the following Covered Drugs: Basaglar, Emgality, Humalog/Insulin Lispro/Lyumjev, Humulin, Rezvoglar, and Zepbound.

Nurse Program violates the THFPA.

Scheme Two: Lilly Provides Reimbursement Support Services to Induce Providers to Write Prescriptions

52. In the second scheme, Lilly offered and continues to offer remuneration to induce recommendations and prescriptions of Lilly drugs over competing or alternative drugs: free reimbursement support services for Providers through its reimbursement support services ("Support Services") program. This remuneration is a tangible, in-kind benefit that greatly reduces, and in some instances eliminates, Providers' administrative costs related to prescribing these drugs.

53. When a Provider writes a prescription, a number of additional steps must be completed before the patient is able to "fill" the prescription at the pharmacy. These steps customarily include:

- Determining whether and to what extent the patient has prescription drug insurance benefits;
- Determining if the drug is on the formulary lists and, if so, the applicable tiers;
- Seeking a coverage determination for the drug from the patient's carrier;
- Appealing any denial of coverage or prior-authorization;
- Communicating this information to the patient; and
- Managing the resultant paper trail.

54. As part of managing a patient's care, it is the Provider's responsibility to complete the numerous steps between the writing of a prescription and the patient's receipt of the drug. These steps are time-consuming, averaging roughly 20 hours per week for a Provider's office.[11] Because completing these tasks requires the attention of the Provider and his or her staff, each task

[11] *See* Christopher P. Morley, David J. Badolato, John Hickner, and John W. Epling, *The Impact of Prior Authorization Requirements on Primary Care Physicians' Offices: Report of Two Parallel Network Studies*, J. Am. Board Fam. Med. (January-February 2013), Vol. 26 no. 1, at 93-95.

bears discrete economic costs to the Provider.

55. For certain prescriptions, a Provider's staff must also work with the patient's insurance carrier to obtain what is known as a "prior authorization." A prior authorization is the requirement that a Provider obtain approval from the patient's health insurance plan before the drug can be dispensed by a pharmacy—or the patient may be required to pay for the medicine "out of pocket."

56. Because it entails advocacy on behalf of the patient, obtaining prior authorization is a responsibility that falls within the Provider's duty of care.[12] Importantly, numerous states, including Texas, have enacted legislation that requires Providers to obtain prior authorizations on behalf of the patients.[13]

57. Further, large Managed Care Organizations, which administer Medicaid plans for the vast majority of Medicaid recipients in Texas, also specifically require the Providers to perform prior authorization services for the drugs they prescribe.[14]

58. Medicaid carriers also use the prior authorization process to contain costs associated with expensive medications. Carriers routinely require Providers to make a case of

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[12] *See* Getting Medical Pre-approval or Prior Authorization, available at https://www.cancer.org/cancer/financial-insurance-matters/managing-health-insurance/getting-medical-pre-approval-or-prior-authorization.html#:~:text=facility%20billing%20department.-,Pre%2Dapproval%20for%20prescriptions,many%20refills%20you%20can%20have (noting that "Pre-authorization is often needed for expensive medicines. Sometimes insurance plans will want you to try a different medicine before they will approve the one your doctor prescribes. They may also limit how much of the medicine you can have at a time, or how many refills you can have.").

[13] *See* Tex. Admin. Code Title 28, § 19.1820; Tex. Admin. Code Title 4, Subtitle I. § 531.073.

[14] *See, e.g.*, Michael Bilhari, M.D., How Prior Authorization Works (Mar. 2, 2020), available at https://www.verywell.com/prior-authorization-1738770 ("Prior authorization in health care is a requirement that a healthcare provider (such as your primary care physician or a hospital) gets approval from your insurance plan before prescribing you medication or doing a medical procedure. … Without prior approval, your health insurance plan may not pay for your treatment (even if it would otherwise be covered by the plan), leaving you responsible for the full bill.").

medical necessity and explain why a less expensive product is not an acceptable alternative.[15] This process is designed to save taxpayer dollars by ensuring that the more expensive medications are prescribed only when needed.

59. As a coalition of healthcare organizations led by the American Medical Association has recognized, coverage determinations, prior authorization, and appeals often entail "very manual, time-consuming processes . . . [that] burden providers (physician practices, pharmacies and hospitals) and divert valuable and scarce resources away from direct patient care."[16] Further, industry research demonstrates that these tasks are time-consuming and costly for Providers. For instance, a study of 12 primary care practices published in 2013 in The Journal of the American Board of Family Medicine concluded that "preauthorization is a measurable burden on physician and staff time."[17]

60. According to another study published in 2009 in Health Affairs, primary care Providers spent a mean of 1.1 hours per week on authorization-related work, primary care nursing staff spent 13.1 hours, and primary care clerical staff spent 5.6 hours.[18] The same study estimated that the overall cost to the healthcare system of all practice interactions with health plans, including authorizations, was between $23 billion and $31 billion annually.

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[15] *See, e.g.*, Kevin B. O'Reilly, *7 prior authorization terms that drive every doctor to distraction* (July 21, 2025*)*, *available at* https://www.ama-assn.org/practice-management/prior-authorization/7-prior-authorization-terms-drive-every-doctor-distraction.

[16] *See Prior Authorization and Utilization Management Reform Principles*, *available at* https://www.ama-assn.org/sites/default/files/media-browser/principles-with-signatory-page-for-slsc.pdf.

[17] *See* Morley, *supra*, at 93.

[18] *See id.* at 95 (citing Lawrence P. Casalino, Sean Nicholson, David N. Gans, Terry Hammons, Dante Morra, Theodore Karrison, Wendy Levinson, *What Does It Cost Physician Practices To Interact With Health Insurance Plans?*, Health Affairs (July-August 2009), Vol. 28 no. 4, at 533-43).

61. Alternatively, if a Provider does not wish to pay its own staff to carry out these administrative tasks, the Provider can outsource them to third-party commercial vendors for a fee. Numerous vendors provide such outsourcing services. As a study conducted by Deloitte on behalf of a large pharmaceutical company demonstrates, medical practices pay up to $98 per initial insurance verification, up to $75 for insurance re-verification, up to $111.82 for prior authorizations, and other à la carte fees:

Activities	Lash	McKesson	Covance	Incumbent Average
Re-verfication	$20.75	$75.00	$50.00	$41.53
Insurance Verification	$98.00	$75.00	$75.00	$88.50
Reimbursement Support - Rate Verification	$68.00	$65.00	$0.00	$62.52
Coding & Reimbursement Assistance	$20.75	$30.00	$12.45	$23.43
Claims Support and Appeals	$104.28	$125.00	$57.78	$108.45
Ad Hoc Support and Consulting	$100.00	$100.00	$1.00	$93.54
Co-Pay Card Program Administration	$1.00	$0.00	$1.00	$0.65
Field Reimbursement Services	$19,180.00	$10,000.00	$1.00	$14,736.15
Site Visit/ Telecon	$2,150.00	$100.00	$1.00	$1,296.80
General Inquiry	$20.75	$15.00	$12.45	$18.21
Injection Network and Location Support	$104.28	$30.00	$12.45	$72.45
Sales Portal	$5,000.00	$100.00	$45,000.00	$5,904.35
Provider Portal	$8,000.00	$2.50	$0.00	$4,696.52
Plan Comparison	$20.75	$125.00	$88.65	$61.44
Send Hotline Material	$0.60	$15.00	$12.45	$6.38
Benefit Summary Call	$0.00	$100.00	$0.00	$34.78
PAP Prescreening and Referrals	$62.00	$30.00	$89.65	$52.67
Prescription Triage	$68.00	$100.00	$12.45	$75.51
Prior Authorization	$68.00	$75.00	$111.82	$73.29
Injection Reminder	$21.00	$15.00	$12.45	$18.36
Analytics and Reporting	$110.00	$100.00	$135.00	$108.15
Sales Rep Hotline	$20.75	$15.00	$12.45	$18.21
Sample/Vouchers	$100.00	$30.00	$12.45	$69.94
CSR Training and On-boarding	$0.00	$100.00	$0.00	$34.78
Language Line	$0.00	$100.00	$1.00	$34.85
Telecommunications	$0.40	$100.00	$1.00	$35.08

62. Thus, whether outsourced or performed in-house, the tasks that must be completed before prescriptions are filled result in significant, tangible administrative costs to Providers. These are direct costs that Providers would have to incur to perform or outsource the burdensome

administrative tasks associated with Support Services.

63. Despite the significant costs associated with Support Services, Providers are not allowed to charge the patient or their insurance provider for such tasks. For example, in Texas, Providers must certify that no charges beyond reimbursement paid under Texas Medicaid for covered services have been, or will be, billed to a patient. Specifically, the Texas Medicaid Provider Procedures Manual makes clear to providers that "Federal regulations prohibit providers from charging clients a fee for completing or filing Medicaid claim forms" and notes that the "cost of claims filing is part of the usual and customary rate for doing business." Further, providers cannot charge "Texas Medicaid clients, their family, or the nursing facility for telephone calls, telephone consultations, or signing forms."[19]

64. Thus, when an office-based Provider receives payment for an office consultation,[20] the payment is intended to compensate the Provider for medical care given *and* administrative tasks associated with that patient's care. These tasks include Support Services.

65. Given that the administrative tasks associated with the provision of Support Services are time-consuming, Providers are less likely to prescribe a drug that imposes an undue burden on support staff because doing so decreases profitability. Conversely, a Provider is much more likely to prescribe a drug if it can be prescribed with little or no administrative burden.

66. To induce Providers to write prescriptions for its products, Lilly offered and continues to offer Support Services to Providers willing to prescribe the Covered Drugs.

67. The availability of Support Services was highlighted by Lilly in sales pitches,

[19] Texas Medicaid Provider Procedures Manual § 1.7.10 (July 2024), *available at* http://www.tmhp.com/Pages/Medicaid/Medicaid_Publications_Provider_manual.aspx.

[20] The technical term for an office visit is "evaluation and management services" or "E/M."

including during sales pitches Lilly has conducted in Harrison County.

68. The availability of Support Services is a key part of the promotional strategy Lilly devised for the Covered Drugs because it creates significant financial incentives for Providers to prescribe the Covered Drugs over competitor products. Indeed, just this year, Lilly sales reps touted Support Services during sales pitches made in Harrison County. By assuming tasks that would otherwise fall on Providers, Lilly saved Providers time, money and resources they would otherwise have had to expend to discharge their duties to their patients.

69. Because it acts to induce Providers to prescribe the Covered Drugs, Lilly's Support Services Program violates the THFPA.

LILLY VIOLATED THE THFPA KNOWINGLY

70. Lilly is a highly sophisticated company with knowledge of the regulatory regimes that are relevant to its business, including the broad prohibitions on kickbacks set out in the THFPA.

71. Lilly is also aware that the Free Nurse and Support Services programs save Providers money and thus create incentives for Providers to prescribe Covered Drugs.

72. During the time period relevant to this petition, Lilly was aware that no regulatory guidance or advisory opinions exempts the Free Nurse and Support Services programs from anti-kickback scrutiny and the reach of the THFPA.

73. Nevertheless, fully aware that—or, at a minimum, deliberately ignorant whether—the activities challenged herein violate the THFPA, Lilly marketed the Covered Drugs using the Free Nurse and Support Services programs.

THE UNLAWFUL SCHEMES RESULTED IN THE PAYMENT OF UNAUTHORIZED CLAIMS BY TEXAS MEDICAID

74. During the relevant time period, Lilly's actions knowingly have caused pharmacies,

PBMs, fiscal intermediaries and others to submit millions of dollars in claims to Texas Medicaid for Covered Drugs provided to Medicaid beneficiaries that were tainted by Lilly's illegal marketing and quid pro quo arrangements, in violation of Texas Medicaid policy. Those tainted claims have caused Texas Medicaid to disburse millions of dollars in reimbursements that were unauthorized as a result of Lilly's unlawful acts under the THFPA and should not have been paid.

REQUESTED RELIEF

CAUSE OF ACTION – VIOLATIONS OF THE TEXAS HEALTH CARE PROGRAM FRAUD PREVENTION ACT

75. Relator restates and incorporates the foregoing facts and allegations as if fully set forth in their entirety.

76. Lilly knowingly committed multiple unlawful acts as defined in the applicable version of THFPA § 36.002, including the following:

(i) Lilly knowingly offered or paid remuneration to induce Providers to prescribe and/or continue to prescribe the Covered Drugs in violation of Texas law. Tex. Hum. Res. Code § 32.039(b)(1-d). Lilly did so to receive benefits or payments under the Texas Medicaid program, which payment was made in whole or in part by Texas Medicaid. In doing so, it violated Tex. Hum. Res. Code § 36.002(13).

(ii) Lilly knowingly offered or paid remuneration to induce Providers to arrange for or recommend the purchase or order of the Covered Drugs to patients in violation of Texas law. Tex. Hum. Res. Code § 32.039(b)(1-e). Defendant did so to receive benefits or payments under the Texas Medicaid program, which payment was made in whole or in part by Texas Medicaid. In doing so, it violated Tex. Hum. Res. Code § 36.002(13).

(iii) Lilly knowingly provided or offered an inducement to Providers for the purpose of influencing their prescriptions of the Covered Products in violation of Texas law. Tex. Hum. Res. Code § 32.039(b)(1-f). Lilly did so to receive benefits or payments under the Texas Medicaid program, which payment was made in whole or in part by Texas Medicaid. In doing so, it violated Tex. Hum. Res. Code § 36.002(13).

77. Plaintiffs seek on behalf of Texas recovery of the value of all payments under the Medicaid program as a result of Lilly's unlawful schemes and acts, together with pre-judgment and post-judgment interest, pursuant to THFPA § 36.052(a).

78. Plaintiffs seek on behalf of Texas civil penalties in accordance with the penalty range prescribed in THFPA § 36.052(a)(3)(B) for each unlawful act committed by Lilly that did not result in injury to an elderly person, or disabled person, or a person younger than 18 years of age, pursuant to THFPA § 36.052(a)(3)(B).

79. Plaintiffs seek on behalf of Texas an additional two times the value of payment(s) and/or benefit(s) unlawfully received by Lilly, pursuant to THFPA § 36.052(a)(4).

80. Plaintiffs request that the Court enter an order pursuant to THFPA § 36.051 permanently enjoining Lilly from committing further unlawful acts.

81. Plaintiffs seek fees, expenses, and costs reasonably incurred in obtaining civil remedies or in conducting investigations in connection with this litigation, including court costs, reasonable attorney fees, witness fees, expert fees, and deposition fees pursuant to THFPA § 36.110.

82. Plaintiffs ask that they be awarded:

A. Expenses, costs, and attorney's fees;

B. Relator's share as provided by the THFPA; and

C. Such other and further relief to which Plaintiffs may show they are entitled, either at law or in equity.

JURY DEMAND

83. Plaintiffs respectfully request a trial by jury pursuant to Rule 216 of the Texas Rules of Civil Procedure.

PRAYER FOR RELIEF

84. Plaintiffs respectfully pray that upon a trial of this case, the Plaintiffs have judgment against Lilly for the civil recoveries, statutory multiples and statutory penalties sought in this petition, pre-judgment interest at the legal rate, entry of an injunction against further unlawful acts, attorneys' fees, litigation and investigation expenses, witness fees, expert fees, deposition fees, costs of court, and such other relief, at law and in equity, to which Plaintiffs are justly entitled.

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Respectfully submitted,

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