UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, and THE STATES OF COLORADO, GEORGIA, MICHIGAN, NORTH CAROLINA, TEXAS, AND WASHINGTON, *ex rel*. JULIANNE NUNNELLY and MATTHEW SHANKS,	)	
Plaintiffs,	)	No. 1:20-cv-11401-PBS
v.	)	
REGENERON PHARMACEUTICALS, INC.,	)	
Defendant.	)	

CONSOLIDATED COMPLAINT IN PARTIAL INTERVENTION OF THE INTERVENING STATES
AGAINST REGENERON PHARMACEUTICALS, INC.

By notice to the Court on March 28, 2024, the States of Colorado, Georgia, Michigan, North Carolina, Texas, and Washington (hereafter jointly referred to as "the Intervening States") partially intervened in the above-captioned case. The Intervening States re-allege and incorporate by reference the allegations made in the United States' Complaint in Intervention Against Regeneron Pharmaceuticals filed on March 28, 2024, (ECF No. 58, hereinafter referred to as the "U.S. Complaint in Intervention") in the above-captioned case on a paragraph-by-paragraph basis as set forth below. The Intervening States further allege as follows with respect to Defendant Regeneron Pharmaceuticals, Inc. ("Regeneron"):

Introduction

1. This is a civil action brought by the Intervening States against Regeneron, which manufactures Eylea, a drug that is medically indicated to treat forms of macular degeneration and

other ophthalmological conditions. The Intervening States bring this action to recover treble damages and civil penalties under their respective state false claims acts, state statutes, and the common law.

2. Since bringing Eylea to market in late 2011 and continuing until the present, Regeneron has paid hundreds of millions of dollars to subsidize Eylea purchases by reimbursing distributors for credit card processing fees—on the condition that the distributors use these payments to lower the effective price they charged for Eylea to doctors and retina practices using credit cards. From 2012 to 2021, Regeneron's credit card fee reimbursements for Eylea purchases exceeded $250 million to just one of its several distributors. Regeneron paid those fees so that doctors and retina practices that purchased Eylea could use credit cards at no additional cost and obtain hundreds of millions of dollars in "cash back" rewards and other credit card benefits on their Eylea purchases. Regeneron's subsidy payments were price concessions that Regeneron should have included in its price reporting to the Centers for Medicare and Medicaid Services ("CMS") for Eylea. However, Regeneron knowingly excluded the credit card processing fee payments in its price reports to CMS, thereby falsely inflating Medicare reimbursement for Eylea.

3. The Intervening States' Medicaid programs relied on Regeneron's price reports to CMS in their respective State Medicaid programs' Eylea reimbursement methodologies. Therefore, Regeneron's exclusion of the credit card processing fee payments in its price reports to CMS also falsely inflated the Intervening States' Medicaid reimbursement for Eylea. Regeneron's conduct, and the resulting harm to the Intervening States' Medicaid programs, is ongoing.

4. The Intervening States re-allege and incorporate by reference the allegations made in Paragraphs 3 through 15 of the U.S. Complaint in Intervention.

5. The Intervening States' Medicaid programs reimburse physician-administered drugs based on the Average Sales Price ("ASP") as reported by the manufacturers and published by CMS. *See* Colo. State Plan Under Title XIX of the Social Security Act, Medical Assistance Program, Attach. 4.19-B, TN. No. 23-0031; Colo. Physician-Administered Drugs ("PAD") Billing Manual;[1] Ga. State Plan Under Title XIX of the Social Security Act, Attach. 4.19-B, TN No. 09-004; Ga. Dep't of Cmty. Health Providers' Administered Drug List ("PADL") Manual § 1001;[2] Mich. State Plan Under Title XIX of the Social Security Act, Medical Assistance Program, Policy and Methods for Establishing Payment Rates, Attach. 4.19-B at 1d, TN. No. 21-0009;[3] N.C. State Plan Under Title XIX of the Social Security Act, Medical Assistance Program, N.C., Attach. 4.19-B, Section 12 at 2;[4] Tex. State Plan Under Title XIX of the Social Security Act, Medical Assistance Program, Attach. 4.19-B at 1-1a.3, 2c.3;[5] Wash. State Plan Under Title XIX of the Social Security Act, Attach. 4.19-B.[6] Therefore, in the same way an overstated ASP inappropriately increases the reimbursement amount for each claim submitted to Medicare, so does an overstated ASP

[1] COLO. DEP'T OF HEALTH CARE POLICY & FIN., *Physician-Administered Drugs (PAD) Billing Manual*, https://hcpf.colorado.gov/pad-manual (last visited June 23, 2024).

[2] GA. DEP'T OF CMTY. HEALTH, *Ga. Medicaid State Plan,* https://medicaid.georgia.gov/organization/about-georgia-medicaid/medicaid-state-plan (last visited June 24, 2024); GA. DEP'T OF CMTY. HEALTH, *PADL Manual*, https://www.mmis.georgia.gov/portal/PubAccess.Provider%20Information/Provider%20Manuals/tabId/18/Default.aspx (last visited June 24, 2024).

[3] MICH. DEP'T OF HEALTH AND HUMAN SERVICES, *Medicaid State Plan*, https://www.michigan.gov/mdhhs/assistance-programs/medicaid/portalhome/resources/michigan-medicaid-state-plan (last visited June 23, 2024).

[4] N.C. DEP'T OF HEALTH AND HUMAN SERVICES, *Medicaid State Plan*, https://medicaid.ncdhhs.gov/documents/medicaid/get-started/state-plan-under-title-xix-social-security-act-medical-assistance-program/download?attachment (last visited June 23, 2024). On March 28, 2024, CMS approved changes to the North Carolina Physician Administered Drug Program ("NC PADP") fee schedule with an effective date of February 1, 2024. The change allows North Carolina to remove language that set (PADP) reimbursement prices in 2015 and allow for rates to be updated. *See* CENTERS FOR MEDICAID & MEDICAID SERVICES, //www.medicaid.gov/sites/default/files/2024-05/NC-24-0012.pdf (last visited June 23, 2024).

[5] TEX. HEALTH AND HUMAN SERVICES COMM'N, *Medicaid State Plan Attachments*, https://apps.hhs.texas.gov/documents/medicaid-chip-state-plan-attachments.pdf (last visited June 23, 2024) (providing that the Texas Medicaid reimbursement method for physician-administered drugs and biologicals is based on the lesser of the billed amount, a percentage of the Medicare rate, or one of the three other methodologies).

[6] WASH. STATE HEALTH CARE AUTHORITY, *Medicaid (Title XIX) State Plan*, https://www.hca.wa.gov/about-hca/programs-and-initiatives/apple-health-medicaid/medicaid-title-xix-state-plan (last visited June 23, 2024).

inappropriately increase the reimbursement amount for each claim submitted to the Intervening States' Medicaid programs.

6. Regeneron thus knowingly submitted false ASP reports and inflated the amount that the Intervening States' Medicaid programs have paid and continue to pay for Eylea claims, causing the submission of tens of thousands of false claims to the Intervening States' Medicaid programs, and resulting in millions of dollars in damages and civil remedies to the Intervening States.

Jurisdiction and Venue

7. This Court has subject matter jurisdiction under 28 U.S.C. § 1345. Additionally, the Court has supplemental jurisdiction over the state causes of action pursuant to 28. U.S.C. § 1367(a). The Court may exercise personal jurisdiction over Regeneron, and venue is appropriate in this Court under 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b), because some of the false or fraudulent acts committed by Regeneron occurred in this District.

Parties

8. The State of Colorado, acting through the Colorado Department of Law ("Colorado") brings this action pursuant to the Colorado Attorney General's authority under the Colorado Medicaid False Claims Act. The Colorado Department of Health Care Policy and Financing ("HCPF"), an agency of the State of Colorado, administers the Colorado Medicaid program.

9. The State of Georgia acting through the Georgia Department of Law ("Georgia") brings this action pursuant to the Attorney General's authority under the Georgia False Medicaid Claim Act ("GFMCA"). The Georgia Department of Community Health administers the Georgia Medicaid program.

10. The State of Michigan ("Michigan") brings this action pursuant to the Michigan Department of Attorney General's authority under the Michigan Medicaid False Claim Act. The Michigan Department of Health and Human Services ("MDHHS"), an agency of the State of Michigan, administers the Medicaid Program in Michigan.[7]

11. The State of North Carolina ("North Carolina") brings this action pursuant to the North Carolina Department of Justice's authority under the North Carolina False Claims Act. The North Carolina Department of Health and Human Services, Division of Health Benefits ("NCDHB") administers the Medicaid program in North Carolina.[8]

12. The State of Texas ("Texas"), by and through the Office of the Attorney General of Texas, brings this action pursuant to the Texas Medicaid Fraud Prevention Act ("TMFPA"), TEX. HUM. RES. CODE Chapter 36.[9] The Texas Health and Human Services Commission ("Texas HHSC"), an agency of the State of Texas, administers the Texas Medicaid program.

13. The State of Washington ("Washington") brings this action on behalf of the State's Medicaid program pursuant to RCW 74.66 et seq., RCW 43.10.030. The Washington State Health Care Authority ("HCA") administers the State's Medicaid program on behalf of the State of Washington. The Washington Attorney General's Medicaid Fraud Control Division ("MFCD") has authority to investigate and prosecute, either civilly or criminally, Medicaid providers who commit fraud. This authority is granted under RCW 43.10.030(1), RCW 43.10.230, RCW 74.670.010, RCW 74.66.040, and 42 U.S.C. § 1396b(q)(3) and (4).

[7] The Michigan Department of Health and Human Services was formerly known as the Department of Community Health.
[8] The Division of Medical Assistance ("NCDMA") previously administered the Medicaid program in North Carolina.
[9] On September 1, 2023, TEX. HUM RES. CODE Ch. 36 was expanded to include state health care programs beyond the Medicaid program. In this action, however, most of the conduct at issue pre-dates September 1, 2023, and the State of Texas seek only remedies with respect to the Medicaid program. Accordingly, the State of Texas refers to the pre-September 1, 2023 version of TEX. HUM. RES. CODE Ch. 36.

14. The Intervening States re-allege and incorporate by reference the allegations made in Paragraphs 17 through 19 of the U.S. Complaint in Intervention.

Background

15. The Intervening States re-allege and incorporate by reference the allegations made in Paragraphs 20 through 24 of the U.S. Complaint in Intervention.

I. The Intervening States' Medicaid Programs

16. Medicaid is a joint federal-state program that provides health care benefits, including, but not limited to, prescription drug coverage, to qualified groups such as the elderly, impoverished or disabled. The federal government offers funding to state Medicaid programs provided they meet certain minimum requirements set forth under the federal Medicaid statute. *See* 42 U.S.C. § 1396a. The amount of federal funding afforded to each state's Medicaid program, otherwise known as the Federal Medical Assistance Percentage ("FMAP"), is based on each state's per capita income compared to the national average. *Id*. § 1396d(b). Each state pays the remaining balance that the FMAP funds do not cover out of the state's budget ("State Share").

17. Each state Medicaid program is required to implement a "State Plan" containing certain specified minimum criteria for coverage and payment of claims in order to qualify for federal funds for Medicaid expenditures. *See* 42 U.S.C. § 1396a.

A. The Colorado Medicaid Program

18. HCPF, an agency of the State of Colorado, has been designated by the Colorado Legislature as the single state agency to administer Colorado's Medicaid program. C.R.S. § 25.5-4-104(1). HCPF is empowered to promulgate rules that are necessary for administering its programs, including Medicaid. C.R.S. § 25.5-1-105 (2), § 25.5-1-201(1)(a).

19. Medical care and services, including physician-administered prescription drugs like Eylea, are reimbursed by the State of Colorado after claims are submitted to the Colorado Medicaid program.

20. Under the Colorado Medicaid program, providers submit claims for reimbursement to HCPF. Claims are defined as a request or demand for money or property, whether under a contract or otherwise, and regardless of whether the state has title to the money or property. *See* C.R.S. § 25.5-4-304.

21. Under C.R.S. § 25.5.-1-303, HCPF's Medical Assistance Board is authorized to adopt rules regarding the implementation of Medicaid programs and the requirements, obligations, and rights of providers of medical services. C.R.S. § 25.5-4-401(1)(a) specifically empowers HCPF to promulgate rules regarding payment to providers.

22. Regeneron's customers[10], including Colorado providers, submit claims for Eylea to HCPF, using claim form known as CMS 1500 / 837 Professional. Among information the provider includes on the CMS 1500 / 837 Professional form are certain five-digit codes, including Healthcare Common Procedure Coding System ("HCPCS") Level II codes, which identify the services rendered and for which reimbursement is sought. The HCPCS code for Eylea is currently J0178.

23. Once HCPF receives a provider claim for Eylea and confirms that any applicable prior authorization criteria have been satisfied, HCPF reimburses the provider based upon the reimbursement methodology set forth in Colorado's State Plan and further described in the Colorado PAD Billing Manual.

[10] As used herein and throughout the Intervening States' Consolidated Complaint, the term "customers" has the same meaning as defined in the U.S. Complaint in Intervention at ¶4.

24. Colorado Medicaid requires compliance with the terms of the claim form as a precondition of government payment. Colorado Medicaid also requires compliance with program policies, along with applicable statutes, regulations, and guidelines (including manuals and bulletins), as a precondition of government payment or reimbursement

25. Colorado's State Plan sets forth HCPF's reimbursement methodology for claims submitted by providers for physician-administered drugs like Eylea: "Physician-administered drugs are reimbursed at the published Medicare Average Sales Price (ASP) Drug Pricing File minus 3.3 percent for drugs included in that file." *See* Colo. State Plan, Attach. 4.19-B (TN No. CO-23-0031); *see also* 42 C.F.R. § 431.18.

26. Colorado also publishes and provides Medicaid Provider Manuals, including the PAD Billing Manual.[11] The PAD Billing Manual mirrors the language in the State Plan: "Effective July 1, 2017, PADs with a published Medicare Average Sales Price (ASP) are paid at the lower of the published ASP minus 3.3 percent or submitted cost. And PAD for which a published ASP does not exist is paid at either the lower of the submitted cost or the wholesale acquisition cost (WAC)."

27. Eylea has had a published ASP at all relevant time periods and, therefore, Colorado's Medicaid program has reimbursed providers, including Regeneron customers, using an ASP-based reimbursement methodology for every claim submitted for Eylea.

B. The Georgia Medicaid Program

28. The Georgia Department of Community Health ("DCH") is responsible for the administration and supervision of the Medicaid program. O.C.G.A. §§ 49-4-140 *et seq.* DCH is charged with "establish[ing] such rules and regulations as may be necessary or desirable in order to execute the state plan and to receive the maximum amount of federal financial participation

[11] Colorado maintains the Medicaid Provider Manuals at https://hcpf.colorado.gov. *See supra* note 1 for Colorado's PAD Billing Manual.

available in expenditures made pursuant to the state plan[.]" O.C.G.A § 49-4-142(a). Thus, DCH sets the rules for the provision of medical services to Georgia Medicaid recipients, the circumstances in which providers can become enrolled in Georgia Medicaid, and how Georgia Medicaid reimburses providers for these claims.

29. Medical care and services, including physician-administered prescription drugs like Eylea, are reimbursed by the State of Georgia after claims are submitted to the Georgia Medicaid program.

30. Under the Georgia Medicaid program, providers submit claims for reimbursement to DCH. Claims are defined as "a bill for services, a line item of service, or all services for one recipient within a bill." *See* Ga. Dep't of Cmty. Health Part I, Policies and Procedures for Medicaid/PeachCare for Kids.

31. Pursuant to 42 C.F.R. § 431.18, Georgia regulations authorize and require that the DCH "publish the terms and conditions for receipt of medical assistance in Policies and Procedures Manuals for each of the categories of services authorized under the State Plan," including reimbursement methodology. Ga. Comp. R. & Regs. R. 350-1-.02(3). These manuals are disseminated to providers enrolled in the applicable category of service, and amendments thereto are effective "as specified by the Department at the time of dissemination." *Id.* Further, DCH maintains current and past versions of the Georgia Medicaid Policies and Procedures manuals online for providers to view.[12]

32. Regeneron's customers, including Georgia providers, submit claims for Eylea to DCH using claim form known as CMS 1500 / 837 Professional. Among information the provider includes on the CMS 1500 / 837 Professional form are certain five-digit codes, including HCPCS

[12] GA. DEP'T OF CMTY. HEALTH, *Medicaid Policies and Procedures Manuals*, https://www.mmis.georgia.gov (last visited June 24, 2024).

Level II codes, which identify the services rendered and for which reimbursement is sought. The HCPCS code for Eylea is currently J0178.

33. Once DCH receives a provider claim for Eylea and confirms that any applicable prior authorization criteria have been satisfied, DCH reimburses the provider based upon the reimbursement methodology set forth in the Georgia PADL Billing Manual. *See,* Ga. Dep't of Cmty. Health Policies and Procedures for Providers' Administered Drug List ("Georgia PADL"); Georgia Medicaid State Plan, Attach. 4.19-B TN: 09-004.[13]

34. The Georgia PADL sets forth the reimbursement methodology for claims submitted by providers for physician-administered drugs like Eylea:

> Effective September 1, 2009, the Department of Community Health amended the maximum allowable reimbursement for approved drugs on the Providers' Administered Drug List (PADL) to the lesser of:
>
> a) The provider's usual and customary charge
>
> b) Average Sales Price (ASP) plus 6%
>
> c) Wholesale Acquisition Cost (WAC) for injectable drugs that do not have ASP pricing, until such time that ASP plus 6% pricing becomes available. Drugs on the PADL that are priced without an ASP rate are denoted by an inverted triangle [▼].
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> Georgia PADL § 1001.[14] *See also,* Georgia Medicaid State Plan, Attach. 4.19-B TN: 09-004.[15]

[13] *See supra* note 2.
[14] This policy was amended in 2017 and 2019. While the 2017 amendment only impacted injectable drugs without an ASP, prior to January 2019 the policy relied on "b) Average Sales Price (ASP) plus 6% as defined January 1st of each year or the ASP + 6% upon the drug's initial availability in the marketplace whichever is later." Current and archived versions of the PADL are maintained at https://www.mmis.georgia.gov.
[15] *See supra* note 2.

35. Eylea has had a published ASP at all relevant time periods and, therefore, Georgia's Medicaid program has reimbursed providers, including Regeneron customers, using an ASP-based reimbursement methodology for every claim submitted for Eylea.

36. Pursuant to § 1932(a)(1)(A) of the Social Security Act, DCH has also partially delegated administration to Care Management Organizations ("CMOs"), which administer health plans and process and pay Medicaid claims to its contracted providers. All of Georgia's CMOs rely on the Georgia PADL in determining reimbursement rates for Eylea and, by extension, rely on Eylea's ASP as reported by Regeneron.

C. The Michigan Medicaid Program

37. Under the Michigan Social Welfare Act, M.C.L. §§ 400.1, *et seq*., the Michigan Department of Health and Human Services or MDHHS (formerly known as the Department of Community Health[16]) administers the Medicaid Program in Michigan. M.C.L. § 400.105.

38. In Michigan, the Medicaid program provides comprehensive health care services to low-income adults and children offered through fee-for-service ("FFS"), through Medicaid Managed Care Organizations ("MCOs"), and through health plans, such as the Healthy Michigan Plan and the MIChild program (all referred to hereafter, collectively, as "Michigan Medicaid").

39. Under the Michigan Medicaid program, medical care and services, including physician-administered prescription drugs like Eylea, are reimbursed by the State of Michigan after claims are submitted to the Michigan Medicaid program. A physician must be paid a reasonable charge for the service rendered. MDHHS determines reasonable charges. Reasonable charges must not be more than those paid in this state for services rendered under Title XVIII.

[16] Throughout the Michigan Social Welfare Act, the statute still refers to MDHHS as the Department of Community Health, but the entities are one in the same.

M.C.L. § 400.109. Title XVIII is defined as Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395 to 1395*lll*.

40. The director of the Department of Community Health is authorized to adopt policies and procedures regarding the implementation of the Michigan Medicaid program and the requirements, obligations, and payment rules for providers of medical services. M.C.L. § 400.111a.

41. Among the payment instructions is a provision that the claims against the program are timely, substantiated, and not false, misleading, or deceptive. Additionally, reimbursement is not made to those providers whose services, supplies, or equipment cost the program in excess of the reasonable value received. M.C.L. § 400.111a.

42. Claims are defined as any attempt to cause the department of community health to pay out sums of money under the Social Welfare Act. M.C.L. § 400.602.

43. Regeneron's customers, including Michigan providers, submit claims for Eylea to Michigan Medicaid, using claim form known as CMS 1500 / 837 Professional. Among information the provider includes on the CMS 1500 / 837 Professional form are certain five-digit codes, including HCPCS Level II codes, which identify the services rendered and for which reimbursement is sought. The HCPCS code for Eylea is currently J0178. Michigan provider claims are processed electronically using the Michigan Medicaid Community Health Automated Medicaid Processing System or "CHAMPS" system.

44. If a provider voluntarily elects to participate in Michigan Medicaid Program, the provider must enroll and comply with numerous statutory and contractual requirements. M.C.L. § 400.111b.

45. As a condition of payment for services rendered, a Michigan Medicaid provider must certify that a claim for payment is true, accurate, prepared with the knowledge and consent of the provider, and does not contain untrue, misleading, or deceptive information. M.C.L. § 400.111(b)(17).

46. The Medicaid Provider Manual is available online[17] and is updated quarterly to reflect policy bulletins issued by the MDHHS. The Provider Manual is organized into chapters and appendices, with specific applicability based on the type of provider. A provider must read and comply with the terms and conditions of the Medicaid Provider Manual from MDHHS.

47. Pursuant to Section 3.16 of the Medicaid Provider Manual, Medicaid covers injectable drugs and biological products administered by a physician in the office, clinic setting, and in the beneficiary's home. For any injectable drug that a practitioner purchases directly through a pharmacy, distributor or wholesaler which is administered in the office, clinic setting, or the beneficiary's home, the injectable drug is considered a physician service rather than a pharmacy benefit.

48. Pursuant to the Michigan State Plan Under Title XIX of the Social Security Act for the Medical Assistance Program, physician-administered drugs and biologicals, like Eylea, that are not paid on a cost or prospective payment basis will be reimbursed in accordance with Medicare Part B payment limits. The State's published fee schedule will be based upon ASP drug pricing files supplied by CMS with updates on a quarterly basis. Policy and Methods for Establishing Payment Rates, Attach. 4.19-B at 1d, TN. No. 21-0009.[18]

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[17] MICH. DEP'T OF HEALTH AND HUMAN SERVICES, Medicaid Provider Manual, https://www.michigan.gov/mdhhs/doing-business/providers/providers/medicaid/policyforms/medicaid-provider-manual (last visited June 23, 2024).

[18] *See supra* note 3.

49. Eylea has had a published ASP at all relevant time periods and, therefore, Michigan's Medicaid program has reimbursed providers, including Regeneron customers, using an ASP-based reimbursement methodology for every claim submitted for Eylea.

D. The North Carolina Medicaid Program

50. The North Carolina Medicaid Program ("NC Medicaid") is authorized by Title XIX of the Social Security Act. 42 U.S.C. §§ 1396, *et seq*. Medicaid is jointly funded by participating states and the federal government and provides health care benefits for certain groups, including the poor and disabled. Each state must have a single state agency to administer the Medicaid program. 42 U.S.C. § 1396a.

51. The North Carolina Division of Health Benefits ("NCDHB") administers the Medicaid program in North Carolina and receives, processes, and pays claims for services under the NC Medicaid program. HHS periodically reimburses NCDHB for the federal share of all qualified NC Medicaid claims and ensures that the state complies with minimum standards in the administration of the program. NCDHB issues NC Medicaid policies, bulletins, and other materials to provide guidance to providers regarding which services are reimbursable by NC Medicaid and how to bill those services. *See* 42 C.F.R. § 431.18.

52. Providers bill NC Medicaid for services provided to NC Medicaid beneficiaries by submitting claim forms electronically to NCDHB through its fiscal agent. This fiscal agent was Computer Sciences Corporation, which later became CSRA Inc. Since April 2018, following an acquisition, CSRA has been known as GDIT.

53. As with Medicare, a NC Medicaid provider must submit an equivalent version of CMS 1500 for claims for reimbursement. Regeneron's customers, including North Carolina Medicaid providers, must submit the CMS 1500 form, or its electronic equivalent, known as the

837P form, for claims for reimbursement. Among information the provider includes on the CMS 1500 or the 837P form are certain five-digit codes, including HCPCS Level II codes, which identify the services rendered and for which reimbursement is sought. The HCPCS code for Eylea currently, and during the relevant period, is J0178.

54. A "claim" is any request or demand, whether under a contract or otherwise, for money or property and whether or not the State has title to the money or property that i) is presented to an officer, employee, or agent of the State or (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the State's behalf or to advance a State program or interest and if the State government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded. N.C. Gen. Stat. § 1-606(2).

55. NC Medicaid requires compliance with the terms of the claim form as a precondition of government payment. NC Medicaid also requires compliance with program policies, along with applicable statutes, regulations, and guidelines, as a precondition of government payment or reimbursement.

56. The North Carolina Physician Administered Drug Program covers drugs purchased for use in an outpatient office setting. NC Medicaid covers the cost of the drug when it is purchased by the same provider administering the drug.

57. North Carolina's State Plan sets forth NC Medicaid's reimbursement methodology for claims submitted for providers for physician administered drugs like Eylea.

58. Pursuant to North Carolina's State Plan under Title XIX of the Social Security Act for the Medical Assistance Program, during the relevant time periods herein, physician administered drugs are reimbursed at the ASP plus six percent (6%) to follow Medicare pricing.

See N.C. State Plan Under Title XIX of the Social Security Act Medical Assistance Program, North Carolina, Attach. 4.19-B, Section 12 at 2.[19]

59. North Carolina publishes and provides Medicaid Provider Manuals, including Billing Manuals.[20]

60. Eylea has had a published ASP at all relevant time periods and, therefore, NC's Medicaid program has reimbursed providers, including Regeneron customers, using an ASP-based reimbursement methodology for every claim submitted for Eylea.

E. The Texas Medicaid Program

61. The state and federal governments fund health care for the poor and disabled through public health assistance programs. Together, the State of Texas and the federal government fund the Medical Assistance Program in Texas, commonly referred to as Texas Medicaid. Texas Medicaid provides vital health coverage to Texas's most vulnerable populations. *See* TEX. HUM. RES. CODE § 32.001. It is a lifeline ensuring that children, pregnant women, elderly adults, and disabled individuals received the medical care they need. *See* 1 TEX. ADMIN. CODE § 358.107; 1 TEX. ADMIN. CODE § 366.307; 1 TEX. ADMIN. CODE § 366.507. Texas Medicaid coverage is provided through FFS or Medicaid MCOs service delivery models.

62. The Texas Health and Human Services Commission ("Texas HHSC"), an agency of the State of Texas, has been designated by the Texas Legislature as the single state agency to administer the Texas Medicaid program and has authority to promulgate rules and other methods of administration governing the program. TEX. GOV'T CODE § 531.021. Texas Medicaid

[19] *See supra* note 4. With an effective date of February 1, 2024, CMS approved an amendment to North Carolina State Plan's Physician Administered Drug Program (PADP) that removed language that set fee schedule rates as of January 1, 2015, and instead allows for rates to be updated. *Id*. The amended language states, in part, that new physician administered drugs are reimbursed at the Average Sales Price (ASP) to follow Medicare pricing. *Id*.

[20] N.C. DEP'T OF HEALTH AND HUMAN SERVICES, *North Carolina's Physician-Administered Drugs ("PAD") Billing Manual*, https://medicaid.ncdhhs.gov/pdp-provider-catalog-finalwithoutradiopharmaceuticals20240325-pdf/download?attachment?attachment (last visited June 24, 2024).

reimburses participating providers for the approved pharmaceuticals they provide to Medicaid patients. The program strives to provide safe and effective health services to beneficiaries while maximizing the efficient use of taxpayer funds within the Texas Medicaid program. *See In re Xerox Corp*., 555 S.W.3d 518, 524 (Tex. 2018).

63. Texas HHSC establishes reimbursement rates for nondiscretionary items and services, including physician-administered drugs. Texas HHSC's Provider Finance Department ("PFD") is responsible for setting Medicaid FFS reimbursement rates, which are paid to providers contracted directly with Texas HHSC for each Medicaid service from claims submitted to the state.

64. Regeneron's customers, including Texas providers, submit claims for Eylea to Texas HHSC, using claim form known as CMS 1500 / 837P. Among information the provider includes on the CMS 1500 / 837P form are certain five-digit codes, including HCPCS Level II codes, which identify the services rendered and for which reimbursement is sought. The HCPCS code for Eylea is currently J0178.

65. The Texas Medicaid State Plan sets forth the permissible reimbursement methodologies for physician-administered drugs and biologicals. *See* Tex. Medicaid State Plan, Attach. 4.19-B at 1-1a.3, 2c.3.[21]

66. To determine the reimbursement methodology for physician-administered drugs, HHSC may consider information such as costs, utilization data, sufficiency, and public input. *See* 1 TEX. ADMIN. CODE § 355.8085(e). Texas Medicaid reimburses physician-administered drugs based on the lesser of the billed amount or the maximum allowable fee as determined by HHSC. HHSC sets the maximum fee in accordance with following methodologies:

> (1) If the drug or biological is considered a new drug or biological (that is, approved for marketing by the Food and Drug Administration within 12 months of implementation as a benefit of Texas Medicaid), it may be

[21] *See supra* note 5.

> reimbursed at an amount equal to 89.5 percent of average wholesale price (AWP).
> (2) If the drug or biological does not meet the definition of a new drug or biological, it may be reimbursed at an amount equal to 85 percent of AWP.
> (3) Vaccines may be reimbursed at an amount equal to 89.5 percent of AWP.
> (4) Infusion drugs furnished through an item of implanted Durable Medical Equipment may be reimbursed at an amount equal to 89.5 percent of AWP.
> (5) Drugs, other than vaccines and infusion drugs, may be reimbursed at an amount equal to 106 percent of the average sales price (ASP).

Id. at § 355.8085 (e) (1-5). *See also* Tex. Medicaid State Plan, Attach. 4.19-B at 1-1a.3, 2c.3

67. The Texas Medicaid Provider Procedures Manual ("TMPPM") explains that "Texas Medicaid reimburses certain providers based on rates published in the Online Fee Lookup ("OFL") and static fee schedules. These rates are uniform statewide and by provider type. According to this type of reimbursement methodology, the provider is paid the lower of the billed charges or the Medicaid rate published in the applicable static fee schedule or OFL." *See* Section 2.2.1 of the TMPPM.[22] Type of service ("TOS") codes payable for each procedure code are available on the OFL and the static fee schedules. *Id*.

68. The static fee schedule and OFL, which are publicly available on the TMHP website,[23] display the allowable reimbursement rate for medical services and the selected procedure code. The procedure code for Eylea, J0178, has been listed on the status fee schedule and OFL since January 2013. The Medicaid rate for this service is reimbursed in accordance with 1 TEX. ADMIN CODE § 355.8085(e) and the Texas Medicaid State Plan.[24]

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[22] TEX. MEDICAID & HEALTHCARE PARTNERSHIP, *Texas Medicaid Provider Procedures Manual ("TMPPM")*, https://www.tmhp.com/sites/default/files/microsites/provider-manuals/tmppm/html/TMPPM/1_02_Texas_Medicaid_Reimbursement/1_02_Texas_Medicaid_Reimbursement.htm (last visited June 24, 2024).
[23] TEX. MEDICAID & HEALTHCARE PARTNERSHIP, *Texas Medicaid Fee Schedule and Online Fee Lookup ("OFL")*, https://public.tmhp.com/FeeSchedules/Default.aspx (last visited June 24, 2024).
[24] *See supra* note 5.

69. Medicaid managed care is an integrated service delivery system administered by MCOs that are contracted by Texas HHSC to provide all covered medically necessary services for managed care clients.[25] The Texas Medicaid MCOs are not required to follow the static fee schedule or OFL but may do so.[26] Texas Medicaid MCOs may instead use proprietary reimbursement structures and alternate reimbursement models to reimburse for Eylea, as reflected in the MCOs contract with a provider.

70. Eylea has had a published ASP at all relevant time periods. The Texas Medicaid program has reimbursed providers, including Regeneron customers, using an ASP-based reimbursement methodology for fee-for-service claims submitted for Eylea from January 1, 2013 to March 31, 2019, September 1, 2020 through February 28, 2021, and again from September 1, 2021 to present. Texas Medicaid MCOs that reimburse for Eylea by following the static fee schedule and OFL have also reimbursed providers, including Regeneron customers, using an ASP-based reimbursement methodology for claims submitted for Eylea from January 1, 2013 to March 31, 2019, September 1, 2020 through February 28, 2021, and again from September 1, 2021 to present.

F. The Washington Medicaid Program

71. Washington State's Medicaid program is a means-tested benefit program providing healthcare coverage to low-income people. It was established pursuant to Title XIX of the Social Security Act §1901. *See also* 42 U.S.C. §§ 1396, *et seq.*; 42 CFR §§ 430.1, *et seq.*; RCW 74.09.035. Medicaid is a joint federal-state program that provides health care and other benefits for certain groups of people, primarily people experiencing poverty and the disabled. The federal government

[25] TEX. MEDICAID & HEALTHCARE PARTNERSHIP, *TMPPM: Medicaid Managed Care Handbook*, at 5, https://www.tmhp.com/sites/default/files/file-library/resources/provider-manuals/tmppm/pdf-chapters/2022/2022-06-june/2_Medicaid_Managed_Care.pdf (last visited June 24, 2024).
[26] *See supra* note 17, at Section 2.2.

provides matching funds and ensures that states participating in the Medicaid program comply with minimum standards. Social Security Act § 1903(a)(1). So long as the state's Medicaid program is administered in compliance with federal requirements, the federal government pays a share of the program costs known as the FMAP. The states pay the remaining portion, known as the State Medical Assistance Percentage (SMAP). While the percentage has changed from year to year, the federal/state percentage share for Washington is typically 45-55.

72. All funds administered through a Medicaid managed care delivery system are paid for by the federal and state governments using dedicated Medicaid program dollars.

73. States participating in the Medicaid program are required to submit a plan to the U.S. Department of Health & Human Services, Centers for Medicare and Medicaid Services (CMS). Social Security Act § 1902; 42 U.S.C. § 1396a. The state plan is a formal, written agreement between a state and the federal government, submitted by the single state agency (SSA) and approved by CMS, describing how the state will administer its Medicaid program. 42 CFR § 431.10.[27]

74. Providers and/or MCOs bill for services and physician-administered drugs provided to Medicaid clients according to HCA's regulations, billing instructions, and the terms of the HCA core provider agreement (CPA) or managed care contracts (MCC). 42 U.S.C. § 1396b(a)(1).[28] For example, "[t]he Agency only pays claims submitted by or on behalf of a supplier or contractor of service that has an approved [CPA] with the agency…." WAC 182-502-0005(1).

[27] *See supra* note 6.

[28] WASH. STATE HEALTH CARE AUTHORITY, *Provider Billing Guides*, https://www.hca.wa.gov/billers-providers-partners/prior-authorization-claims-and-billing/provider-billing-guides-and-fee-schedules (last visited June 24, 2024).

75. HCA reimburses drugs administered in the provider's office and billed using the drug-specific HCPCS code and the product-specific NDC at the rates showing on Medicare's drug pricing files (ASP pricing files.). *See* Washington State Plan, Attach. 4.19-B.[29]

76. The Washington State Medicaid program relies on providers complying with the terms of the CPA on an ongoing basis, and specifically in their submission of claims for payment. In short, providers are expected to submit truthful and accurate claims. Claims tainted by fraud or inducements are ineligible for payment and punishable by criminal and/or civil action.

II. ASP and Reimbursement Rates for Medicare Part B Drugs

77. The Intervening States re-allege and incorporate by reference the allegations made in Paragraphs 25 through 30 of the U.S. Complaint in Intervention.

III. History of ASP Methodology

78. The Intervening States re-allege and incorporate by reference the allegations made in Paragraphs 31 through 36 of the U.S. Complaint in Intervention.

IV. The Federal False Claims Act

79. The Intervening States re-allege and incorporate by reference the allegations made in paragraphs 37 through 40 of the U.S. Complaint in Intervention

V. The Intervening States' False Claims Acts and State Statutes

80. Each of the Intervening States has its own state false claims act or state statute that imposes liability for, among other things, knowingly submitting, or causing to be submitted, false or fraudulent claims to the States' Medicaid programs, and for knowingly making, using, or causing to be made or used, false records or statements material to false or fraudulent claims made to the States' Medicaid programs.

[29] *See supra* note 6.

A. The Colorado Medicaid False Claims Act

81. The Colorado Medicaid False Claims Act ("CMFCA") closely follows the wording of the federal False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733. The CMFCA provides, in pertinent part, that a person is liable to the State of Colorado for a civil penalty plus three times the amount of damages that the State sustains because of the act of the person, if the person:

(1)(a) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or]

(1)(b) Knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim . . .

C.R.S. § 25.5-4-305(1)(a) & (b). Since August 7, 2013, the civil penalties in the CMFCA tracked the penalties provided by the federal FCA.

82. As used in the CMFCA,

> (1)(a) "Claim means a request or demand for money or property . . . under the "Colorado Medical Assistance Ace" [Medicaid program] that is:
>
> (I) Presented to an officer, employee, or agent of the state; or
> (II) Made to a contractor, grantee, or other recipient if the money or property is to be spent or used on the state's behalf or to advance a program or interest of the state and if the state:
>
> (A) Provides or has provided any portion of the money or property requested or demanded; or
>
> (B) Will reimburse the contractor, grantee, or other recipient for any portion of the money or property that is requested or demanded.

C.R.S. § 25.5-4-304(1).

83. "Knowing" and "knowingly" require no proof of specific intent to defraud (C.R.S. § 25.5-4-304(3)(b)) and mean that a person, with respect to information:

> (I) Has actual knowledge of the information;

(II) Acts in deliberate ignorance of the truth or falsity of the information;

or

(III) Acts in reckless disregard of the truth or falsity of the information.

C.R.S. § 25.5-4-304(3)(a).

84. "Material" is defined in the CMFCA as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." C.R.S. § 25.5-4-304(4).

B. The Georgia False Medicaid Claims Act

85. The Georgia False Medicaid Claims Act ("GFMCA") closely follows the wording of the FCA, 31 U.S.C. § 3729, *supra*. The GFMCA provides, in pertinent part, that:

> Any person who:
>
> (a)(1) Knowingly presents or causes to be presented to the Georgia Medicaid program a false or fraudulent claim for payment or approval;
>
> (a)(2) Knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim; [or]
>
> (a)(3) Conspires to commit a violation of paragraph (1) [or] (2) . . .

is liable to the State of Georgia for three times the amount of damages sustained by the Georgia Medicaid program, plus a civil penalty per violation. O.C.G.A § 49-4-168.1. The civil penalties in the GFMCA mirror those of the federal FCA, as described *supra*. See *Id.*

86. As used in the GFMCA,

"knowing" and "knowingly" require no proof of specific intent to defraud and mean that a person, with respect to information:

(A) Has actual knowledge of the information;

(B) Acts in deliberate ignorance of the truth or falsity of the information; or

(C) Acts in reckless disregard of the truth or falsity of the information.

O.C.G.A. § 49-4-168(2).

87. The GFMCA defines "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." O.C.G.A. § 49-4-168(3).

C. The Michigan Medicaid False Claims Act

88. The Michigan Medicaid False Claim Act ("MMFCA") largely parallels the wording of the FCA, 31 U.S.C. § 3729, *supra*. The MMFCA provides, in pertinent part, that a person is liable to the State of Michigan for a civil penalty plus three times the amount of damages that the State sustains because of the act of the person, if the person:

> (1) makes or presents or causes to be made or presented to an employee or officer of this state a claim under the social welfare act, 1939 PA 280, M.C.L. §§ 400.1 to 400.119b, upon or against the state, knowing the claim to be false. M.C.L. § 400.607(1).
>
> (2) knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state pertaining to a claim presented under the social welfare act. M.C.L. § 400.607(3).
>
> (3) enters into an agreement, combination, or conspiracy to defraud the state by obtaining or aiding another to obtain the payment or allowance of a false claim.

M.C.L. § 400.606.

89. M.C.L. § 400.602 provides the definitions used in the MMFCA, and states, in pertinent part;

a) A benefit means the receipt of money, goods, or anything of pecuniary value.

b) A "claim" means any attempt to cause the department of community health to pay out sums of money under the social welfare act.

c) Something is "false" if it is wholly or partially untrue or deceptive.

d) "Deceptive" is further defined to mean making a claim or causing a claim to be made under the social welfare act that contains a statement of fact or that fails to reveal a fact, which statement or failure leads the department to believe the represented or suggested state of affair to be other than it actually is.

e) A "person" includes an individual, corporation, association, partnership or other legal entity.

90. "Knowing" and "knowingly" require no proof of specific intent to defraud and mean that a person, with respect to information:

(I) Has actual knowledge of the information (or should be aware of the information); or

(II) Acts in deliberate ignorance of the truth or falsity of the information; or

(III) Acts in reckless disregard of the truth or falsity of the information.

91. The civil penalties outlined in M.C.L. § 400.612 largely track the penalties provided in the federal FCA, including treble damages and a civil penalty per false claim.

D. The North Carolina False Claim Act

92. The North Carolina False Claims Act ("NCFCA") is modeled after the federal False Claims Act. The NCFCA states, in pertinent part, that any person who:

> (a)(1) Knowingly presents or caused to be presented a false or fraudulent claim for payment or approval;
> (a)(2) Knowingly makes, uses, or caused to be made or used, a false record or statement material to a false or fraudulent claim;
> (a)(3) Conspires to commit a violation of subdivision (1), (2), (4), (5), (6), or (7); . . . [or]

> (a)(7) Knowingly makes, uses, or caused to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the State, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the State . . .

shall be liable to the State for three times the amount of damages that the State sustains because of the act of that person. A person . . . shall be liable to the State for the costs of a civil action brought to recover any of those penalties or damages and shall be liable to the State for a civil penalty of not less than five thousand five hundred dollars ($5,500) and not more than eleven thousand dollars ($11,000), as may be adjusted by Section 5 of the Federal Civil Penalties Inflation Adjustment Act of 1990, P.L. 101-410, as amended, for each violation. N.C.G.S. § 1-607.

93. For purposes of the NCFCA,

> "Knowing" and "knowingly." – Whenever a person, with respect to information, does any of the following:
> a. Has actual knowledge of information
> b. Acts in deliberate ignorance of the truth or falsity of the information.
> c. Acts in reckless disregard of the truth or falsity of the information.
> Proof of specific intent to defraud is not required . . .

N.C.G.S. § 1-606(4).

94. The NCFCA defines "material" to mean "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." N.C.G.S. § 1-606(5).

E. The Texas Medicaid Fraud Prevention Act

95. To target fraud against the Texas Medicaid program and protect its integrity, the Texas Medicaid Fraud Prevention Act ("TMFPA") grants the Attorney General of Texas with authority to investigate and pursue actions against persons who commit certain unlawful acts prohibited by the statute. *See* TEX. HUM. RES. CODE §§ 36.001, *et seq*. The TMFPA permits Texas to recover civil remedies and civil penalties for fraud associated with unlawful acts and imposes administrative sanctions such as suspension from Texas Medicaid. *Id*. §§ 36.052, 36.005(b).

96. While the TMFPA and federal FCA share similar objectives, the TMFPA differs from the FCA in two important ways: (1) the TMFPA defines "unlawful acts" that are actionable and (2) the TMFPA permits the state to recover civil remedies and civil penalties rather than "damages." *Xerox*, 555 S.W.3d at 526-35 (discussing the relevant provision under the heading "The Remedies in section 36.052 Are Not Damages"). The remedies include the amount of any payment or the value of any monetary or in-kind benefit provided under the Medicaid program, directly or indirectly, as a result of the unlawful act, including any payment made to a third party; two times the amount of the payment or value of the benefit described above; interest on the amount of the payment or the value of the benefit described above; and a civil penalty. TEX. HUM. RES. CODE § 36.052(a).

97. A person is liable under the TMFPA if the person commits certain unlawful acts, many of which are not conditioned on the person's submission of a claim for payment to Texas Medicaid. Rather, a person commits an unlawful act as defined under the TMFPA by, among other things:

A. Knowingly making or causing to be made a false statement or misrepresentation of a material fact to permit a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized. TEX. HUM. RES. CODE § 36.002(1).

B. Knowingly concealing or failing to disclose information that permits a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized. TEX. HUM. RES. CODE § 36.002(2).

> C. Knowingly making or causing to be made a false statement or misrepresentation of material fact concerning: information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program. TEX. HUM. RES. CODE § 36.002(4)(B).

98. A person acts "knowingly" with respect to information if the person (i) has actual knowledge of the information; (ii) acts with conscious indifference to the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information. *Id.* at § 36.0011(b). The TMFPA does not require Texas to prove that Regeneron acted with specific intent to commit an unlawful act in order to prove that Regeneron acted knowingly. *Id*. at § 36.0011(b).

99. A fact or information is "material" if it has "a natural tendency to influence or [is] capable of influencing." *Id.* at § 36.001(5-a). Unlike the FCA, a fact or information does not have to be tied to "the payment or receipt of money or property" in order to be material under the TMFPA. *Compare* TEX. HUM. RES. CODE ANN. § 36.001(5-a), *with* 31 U.S.C. § 3729(b)(4).

F. The Washington State False Claims Act

100. The Washington State False Claims Act ("FCA") is modeled after the federal False Claims Act. The Washington State FCA states, in pertinent part, that a person is liable to the State of Washington if the person:

> (a) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval [or];
>
> (b) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

RCW 74.66.020(1)(a) and (b). These terms are identical to the federal False Claims Act.

101. The Washington False Claims Act's knowledge definitions are also functionally identical to the federal False Claims Act, stating that, "(k)nowing" and "knowingly" mean that a person, with respect to information:

> (i) Has actual knowledge of the information;
>
> (ii) Acts in deliberate ignorance of the truth or falsity of the information; or
>
> (iii) Acts in reckless disregard of the truth or falsity of the information.
>
> (b) "Knowing" and "knowingly" do not require proof of specific intent to defraud.

RCW 74.66.010(7)(a) and (b).

102. The consequences for liability under the Washington FCA are also the same as the federal False Claims Act, with the Washington FCA specifying that a person is liable to the State of Washington for three times the amount of damages that the Government sustains because of the act of that person, plus additional civil penalties for each violation. RCW 74.66.020(1).

Factual Allegations

103. The Intervening States re-allege and incorporate by reference the allegations made in Paragraphs 41 through 122 of the U.S. Complaint in Intervention.

I. Regeneron Submitted False ASP Reports to CMS and Caused the Submission of Materially False Claims to the Colorado, Georgia, Michigan, North Carolina, and Washington State Medicaid Programs

A. By Knowingly Submitting False ASP Reports to CMS, Regeneron Submitted False Statements Material to False Claims to the State Medicaid Programs of Colorado, Georgia, Michigan, North Carolina, and Washington

104. The Intervening States re-allege and incorporate by reference the allegations made in Paragraphs 123 through 126 of the U.S. Complaint in Intervention.

105. The Intervening States' Medicaid programs relied on the accuracy of Regeneron's ASP submissions to CMS.

106. Regeneron's inflated ASP reports thereby caused the reimbursements for Eylea by the Medicaid programs of Colorado, Georgia, Michigan, North Carolina, and Washington to be materially inflated.

B. Regeneron's False ASP Reports Caused the Submission of False Claims to the State Medicaid Programs of Colorado, Georgia, Michigan, North Carolina, and Washington

107. Regeneron's failure to properly report credit card fees as price concessions caused the submission of millions of dollars of false claims to the State Medicaid programs of Colorado, Georgia, Michigan, North Carolina, and Washington.

108. At all relevant times, Regeneron knew that its customers submitted claims to Medicaid for Eylea. Regeneron knew that the ASP it reported to CMS for Eylea impacted the reimbursement amounts the Intervening States' Medicaid programs paid for Eylea claims.

C. Regeneron's Violations Were Material to the Medicaid Payment Decisions of the States of Colorado, Georgia, Michigan, North Carolina, and Washington

109. Because the Colorado, Georgia, Michigan, North Carolina, and Washington States' Medicaid reimbursement rates for Eylea were set based on ASP, Regeneron's falsely inflated ASP reports for Eylea were material to the amount the Medicaid programs paid for each Eylea claim. By inflating Eylea's ASP, Regeneron caused the Intervening States' Medicaid programs to reimburse each Eylea claim at a higher, inflated amount.

II. Regeneron Committed TMFPA Unlawful Acts in the Submission of False ASP Reports to CMS that Resulted in Inflated Reimbursements by Texas Medicaid

109. The Texas Medicaid program relied on the accuracy of Regeneron's ASP submissions to CMS. Regeneron's false ASP reports thereby caused the reimbursements for Eylea

by the Texas Medicaid program to be inflated. Regeneron knew that the ASP it reported to CMS for Eylea impacted the reimbursement amount that Texas Medicaid paid for Eylea claims. Because Texas Medicaid's reimbursement rates for Eylea were set based on ASP, Regeneron's falsely inflated ASP reports for Eylea constituted unlawful acts in violation of the TMFPA.

III. Intervening States' Damages/Civil Remedies

A. Colorado

110. Between January 1, 2015 and March 31, 2024, the Colorado Medicaid program reimbursed providers over $30,000,000 for more than ten thousand fee-for-service claims for Eylea. Colorado Medicaid continues to reimburse claims for Eylea through the present.

111. At all relevant times, Regeneron knew that its customers submitted claims to Colorado Medicaid for Eylea. Regeneron knew that the ASP it reported for Eylea impacted the reimbursement amounts Medicaid paid for Eylea claims.

112. The table below includes representative claims submitted to and paid by Colorado Medicaid for Eylea from the period during which Regeneron was falsely inflating Eylea's ASP.

Beneficiary State	Beneficiary Initials	Date of Service	Procedure Code	Medicaid Billed Amount	Medicaid Allowed Amount	Medicaid Paid Amount
CO	T.G.	7/8/2015	J0178	$6,012.50	$2,010.22	$2,010.22
CO	A.Z.	12/22/2016	J0178	$4,757.63	$1,307.35	$1,307.35
CO	A.A.	5/16/2017	J0178	$3,922.00	$2,010.22	$2,010.22
CO	V.E.	8/20/2018	J0178	$3,922.00	$1,871.48	$1,871.48
CO	M.R.	10/1/2019	J0178	$3,922.00	$1,842.08	$1,842.08
CO	S.L.	7/20/2020	J0178	$8,890.00	$2,142.74	$2,142.74
CO	W.S.	8/27/2021	J0178	$2,400.00	$1,772.34	$1,772.34
CO	F.Z.	12/5/2022	J0178	$2,400.00	$1,746.40	$1,746.40

CO	J.G.	10/10/2023	J0178	$2,400.00	$1,679.18	$1,679.18
CO	G.C.	3/13/2024	J0178	$2,400.00	$1,667.64	$1,667.64

B. Georgia

113. Between January 2013 and October 2021, the Georgia Medicaid Program reimbursed providers over $11,000,000 for over seventeen thousand claims for Eylea. Georgia Medicaid continues to reimburse claims for Eylea through the present.

114. At all relevant times, Regeneron knew that its customers submitted claims to Georgia Medicaid for Eylea. Regeneron knew that the ASP it reported for Eylea impacted the reimbursement amounts Medicaid paid for Eylea claims.

115. The table below includes representative claims to Georgia Medicaid for Eylea from the period during which Regeneron was falsely inflating Eylea's ASP.

Beneficiary State	Beneficiary Initials	Date of Service	Procedure Code	Medicaid Billed Amount	Medicaid Allowed Amount	Medicaid Paid Amount
GA	M.P.	3/5/2013	J0178	$4200.00	$1961.00	$1961.00
GA	D.T.	6/4/2014	J0178	$2100.00	$1961.00	$1961.00
GA	N.G	10/21/2015	J0178	$7900.00	$3922.00	$3922.00
GA	S.U.	4/11/2016	J0178	$3950.00	$1961.00	$1961.00
GA	C.P.	12/7/2017	J0178	$3960.00	$3912.36	$3912.36
GA	G.T.	2/15/2018	J0178	$4200.00	$1943.90	$1,943.90
GA	R.N.	7/31/2019	J0178	$1980.00	$1914.72	$1914.72
GA	T.B.	1/21/2020	J0178	$4200.00	$1890.06	$1890.06
GA	H.S.	5/18/21	J0178	$4200.00	$1837.74	$1837.74
GA	M.C.	12/13/22	J0178	$4200.00	$1806.00	$1806.00
GA	K.L.	3/28/23	J0178	$4200.00	$1796.66	$1796.66

GA	D.M.	5/29/24	J0178	$4200.00	$1682.26	$1682.26

C. Michigan

116. Between January 2013 and June 3, 2024, the Michigan Medicaid Program reimbursed providers over $54,000,000 for Eylea. This accounts for over 50,000 claims for Eylea. Michigan Medicaid continues to reimburse claims for Eylea through the present.

117. At all relevant times, Regeneron knew that its customers submitted claims to Michigan Medicaid for Eylea. Regeneron knew that the ASP it reported for Eylea impacted the reimbursement amounts Medicaid paid for Eylea claims.

118. The table below includes representative claims submitted to and paid by Michigan Medicaid for Eylea from the period during which Regeneron was falsely inflating Eylea's ASP.

Beneficiary State	Beneficiary Initials	Date of Service	Procedure Code	Medicaid Billed Amount	Medicaid Allowed Amount	Medicaid Paid Amount
MI	V.S.	5/29/2013	J0178	$2160.00	$1961.00	$1961.00
MI	S.M.	9/30/2014	J0178	$2942.00	$1961.00	$1961.00
MI	R.E.	8/31/2015	J0178	$5000.00	$3922.00	$3922.00
MI	A.S.	3/28/2016	J0178	$5000.00	$3922.00	$3922.00
MI	V.M.	4/3/2017	J0178	$5900.00	$1960.28	$1960.28
MI	D.J.	1/2/2018	J0178	$2500.00	$1,943.90	$1,943.90
MI	Y.P.	1/7/2019	J0178	$7480.00	$1927.08	$1927.08
MI	H.S.	7/1/2020	J0178	$6000.00	$3727.08	$3727.08
MI	D.U.	10/1/21	J0178	$2,500.00	$1835.88	$1835.88
MI	E.S.	2/10/22	J0178	$2,500.00	$1831.50	$1831.50
MI	P.B.	6/14/23	J0178	$5,000.00	$3574.20	$3574.20
MI	J.R.	5/8/24	J0178	$4,320.00	$3364.52	$3364.52

D. North Carolina

119. From January 2013 to October 2021, the North Carolina Medicaid Program reimbursed providers over $23,000,000 for more than 29,000 claims for Eylea. North Carolina continues to reimburse for Eylea through to the present.

120. Regeneron's failure to properly report credit card fees as price concessions caused the submission of thousands of false claims to NC Medicaid.

121. At all relevant times, Regeneron knew that its customers submitted claims to North Carolina Medicaid for Eylea. Regeneron knew that the ASP it reported for Eylea impacted the reimbursement amounts Medicaid paid for Eylea claims.

122. The table below includes representative examples of claims to North Carolina Medicaid for Eylea from the period during which Regeneron was falsely inflating Eylea's ASP:

Beneficiary State	Beneficiary Initials	Date of Service	Procedure Code	Medicaid Billed Amount	Medicaid Allowed Amount	Medicaid Paid Amount
NC	J.B.	9/28/2012	J0178	$535.00	$148.72	$148.72
NC	M.H.	1/10/2013	J0178	$1,350.00	$101.22	$101.22
NC	M.A.	2/19/2014	J0178	$2,562.50	$1,890.20	$468.02
NC	M.C.	6/10/2015	J0178	$6,070.00	$3,958.99	$697.09
NC	K.I.	9/30/2016	J0178	$22,200.00	$3,574.20	$520.57
NC	V.N.	3/3/2017	J0178	$4,600.00	$3,742.60	$668.12
NC	J.S.	3/21/2018	J0178	$2,405.00	$1,871.30	$347.28
NC	A.B.	2/22/2019	J0178	$2,500.00	$1,871.30	$360.47
NC	B.P.	5/15/2020	J0178	$2,250.00	$1,964.86	$375.38
NC	B.M.	5/5/2021	J0178	$2,500.00	$1,964.86	$367.55

E. Texas

123. From January 1, 2013 to March 31, 2019, September 1, 2020 through February 28, 2021, and again from September 1, 2021 to present, the Texas Medicaid Program reimbursed providers over $9,000,000 for more than 23,000 claims for Eylea using an ASP-based reimbursement methodology.

124. At all relevant times, Regeneron knew that its customers submitted claims to Texas Medicaid for Eylea. Regeneron knew that the ASP it reported for Eylea impacted the reimbursement amounts Medicaid paid for Eylea claims.

125. The table below includes representative examples of claims to Texas Medicaid for Eylea from the period during which Regeneron was falsely inflating Eylea's ASP.

Beneficiary State	Beneficiary Initials	Date of Service	Procedure Code	Medicaid Billed Units	Medicaid Billed Amount	Medicaid Paid Amount
TX	Q.P.	3/6/2013	J0178	2	$2,400.00	$314.54
TX	A.O.	2/4/2014	J0178	2	$2,600.00	$345.92
TX	P.F.	2/16/2015	J0178	2	$3,000.00	$384.36
TX	J.H.	1/15/2016	J0178	2	$5,884.00	$1,921.78
TX	J.O.	4/7/2017	J0178	2	$3,535.00	$384.91
TX	J.W.	4/17/2018	J0178	2	$3,000.00	$387.52
TX	D.Z.	3/5/2019	J0178	2	$4,000.00	$385.41
TX	D.M.	12/3/2020	J0178	2	$1,890.10	$371.30
TX	M.G.	10/6/2021	J0178	2	$4,589.72	$367.18
TX	K.R.	1/7/2022	J0178	2	$4,810.00	$1,843.52
TX	R.R.	6/29/2023	J0178	2	$4,000.00	$357.42

F. Washington

126. From January 1, 2013 to present the Washington Medicaid Program reimbursed providers over $48,000,000 for Eylea.

127. Regeneron's failure to properly report credit card fees as price concessions caused the submission of false claims to Washington Medicaid.

128. At all relevant times, Regeneron knew that its customers submitted claims to Washington Medicaid for Eylea. Regeneron knew that the ASP it reported for Eylea impacted the reimbursement amounts Medicaid paid for Eylea claims.

129. The table below includes representative claims to Washington Medicaid for Eylea from the period during which Regeneron was falsely inflating Eylea's ASP:

Beneficiary State	Beneficiary Initials	Date of Service	Procedure Code	Medicaid Billed Amount	Medicaid Allowed Amount	Medicaid Paid Amount
WA	A.W.	12/5/2013	J0178	$2750.00	$1961.00	$392.20
WA	L.J.	10/10/2014	J0178	$3000.00	$1929.62	$392.20
WA	B.J.	9/30/2015	J0178	$2200.00	$1961.00	$392.20
WA	A.R.	9/14/2016	J0178	$2030.00	$1961.00	$423.58
WA	J.K.	5/31/2017	J0178	$2400.00	$1960.28	$1960.28
WA	S.K.	6/27/2018	J0178	$4300.00	$1937.58	$1937.58
WA	E.O.	7/31/2019	J0178	$2750.00	$1884.09	$382.95
WA	D.H.	8/17/2020	J0178	$4140.00	$1863.54	$1863.54
WA	I.O.	2/10/2021	J0178	$4300.00	$1843.51	$368.70
WA	J.M.	4/22/2022	J0178	$3000.00	$1828.40	$1828.40
WA	G.L.	9/19/2023	J0178	$2400.00	$1751.34	$1751.34

CAUSES OF ACTION

CLAIMS OF THE STATE OF COLORADO

Count I
Colorado Medicaid False Claims Act: Causing False or Fraudulent Claim)
(C.R.S. § 25.5-4-305(1)(a))

130. Colorado realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

131. By virtue of the acts described above, Regeneron violated the Colorado Medicaid False Claims Act and knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval to the Colorado Medicaid program in violation of C.R.S. § 25.5-4-305(1).

That is, Regeneron knowingly caused the Colorado Medicaid program to pay inflated reimbursement amounts for each Eylea claim.

132. The State of Colorado, by and through the Colorado Medicaid program, and unaware of Regeneron's conduct, paid the claims submitted for Eylea by healthcare providers.

133. Colorado Medicaid's program payment of the false and fraudulent claims was reasonable and foreseeable result of Regeneron's conduct.

134. By reason of the foregoing, the State of Colorado has sustained damages in a substantial amount to be determined at trial and is entitled to treble damages plus a civil penalty for each false or fraudulent claim. Regeneron is also liable to the State of Colorado for the costs of this civil action to recover damages/penalties.

Count II
Colorado Medicaid False Claims Act: False Statements Material to False Claims (C.R.S. § 25.5-4-305(1)(b))

135. The State of Colorado realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

136. Regeneron knowingly made, used, or caused to be made or used false records or statements that were material to false or fraudulent claims for payment to the Colorado Medicaid

program in violation of C.R.S. § 25.5-4-305(1)(b); that is, Regeneron knowingly created and submitted false and fraudulent inflated ASP reports to CMS.

137. The fraudulent ASP reports were material to, and Colorado Medicaid actually relied on them in, determining Colorado Medicaid reimbursement for claims for Eylea.

138. Payment of the false and fraudulent claims was a reasonable and foreseeable consequence of Regeneron's statements and actions.

139. By reason of the foregoing, the State of Colorado has sustained damages in a substantial amount to be determined at trial and is entitled to treble damages plus a civil penalty for each false or fraudulent claim. Regeneron is also liable to the State of Colorado for the costs of this civil action to recover damages/penalties.

CLAIMS OF THE STATE OF GEORGIA

Count III
False Claims in Violation of O.C.G.A. § 49-4-168.1(a)(1)

140. The State of Georgia realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

141. Regeneron knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval to the Georgia Medicaid program in violation of O.C.G.A. § 49-

4-168.1(a)(1). That is, Regeneron knowingly caused the Georgia Medicaid program to pay inflated reimbursement amounts for each Eylea claim.

142. The State of Georgia, by and through the Georgia Medicaid program, and unaware of Regeneron's conduct, paid the claims submitted for Eylea by healthcare providers.

143. Georgia Medicaid's payment of the false and fraudulent claims was the reasonable and foreseeable result of Regeneron's conduct.

144. By reason of the false or fraudulent claims, the State of Georgia has sustained damages in a substantial amount to be determined at trial and is entitled to treble damages plus a civil penalty for each false or fraudulent claim.

Count IV
False Claims in Violation of O.C.G.A. § 49-4-168.1(a)(2)

145. The State of Georgia realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

146. Regeneron knowingly made, or used, or caused to be made or used, false records or statements material to false or fraudulent claims for payment to the Georgia Medicaid Program

in violation of O.C.G.A. § 49-4-168.1(a)(2). That is, Regeneron knowingly created and submitted false and fraudulent inflated ASP reports to CMS.

147. The fraudulent ASP reports were material to, and Georgia Medicaid actually relied on them in, determining Georgia Medicaid reimbursement for claims for Eylea.

148. Payment of the false and fraudulent claims was a reasonable and foreseeable consequence of Regeneron's statements and actions.

149. By reason of these false records or statements, the State of Georgia has sustained damages in a substantial amount to be determined at trial and is entitled to treble damages plus a civil penalty for each false or fraudulent claim.

CLAIMS OF THE STATE OF MICHIGAN

Count V
Michigan Medicaid False Claim Act: Making or Presenting A False Claim M.C.L. § 400.607(1)

150. Michigan realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

151. As set forth above, Regeneron, by and through their agents, officers, and employees, made, presented, or caused to be made or presented to an employee or officer of the State of Michigan a claim under the social welfare act, 1939 PA 280, M.C.L. §§ 400.1 to 400.119b, upon or against the State, knowing the claim to be false, in violation of M.C.L § 400.607(1).

152. By virtue of the acts described above, Regeneron violated the Michigan Medicaid False Claims Act and knowingly caused false claims to be made, used and presented to the State of Michigan. That is, Regeneron knowingly caused the Michigan Medicaid program to pay inflated reimbursement amounts for each Eylea claim.

153. Regeneron knowingly created and submitted false and fraudulent inflated ASP reports to CMS. The fraudulent ASP reports were material to, and Michigan Medicaid actually relied on them in, determining Michigan Medicaid reimbursement for claims for Eylea.

154. Michigan Medicaid's program payment of the false and fraudulent claims was reasonable and foreseeable result of Regeneron's conduct.

155. By reason of the foregoing, the State of Michigan suffered actual damages because of Regeneron's wrongful conduct in an amount to be determined at trial and therefore is entitled under the False Claims Act to treble damages plus a civil penalty of between $5,000 and $10,000 for each false or fraudulent claim pursuant to M.C.L § 400.612(1).

156. The attorney general for the State of Michigan is also entitled to all costs the State of Michigan incurs in the litigation and recovery of Michigan Medicaid restitution under this act, including the cost of investigation and attorney fees, pursuant to M.C.L § 400.610b(1).

Count VI
Unjust Enrichment

157. The State of Michigan re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

158. By reporting inflated ASP figures to CMS for Eylea, Regeneron was able to retain profits for Eylea and avoid paying monies owed to Michigan.

159. By retaining the use and enjoyment of the monies that should have been paid to Michigan, Regeneron has been unjustly enriched at Michigan's expense in an amount to be determined at trial, which, under the circumstances, in equity and good conscience, and as dictated by the needs of justice and fairness, should be returned to the Michigan or would be unconscionable for Regeneron to retain.

CLAIMS OF THE STATE OF NORTH CAROLINA

Count VI
North Carolina False Claims Act
Presenting or Causing False or Fraudulent Claim
(N.C. Gen. Stat. § 1-607(a)(1))

160. North Carolina realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

161. Regeneron knowingly presented, or causing to be presented, false or fraudulent claims for payment or approval to the North Carolina Medicaid Program in violation of N.C. Gen. Stat. § 1-607(a)(1). Regeneron knowingly caused the NC Medicaid program to pay inflated reimbursement amounts for each Eylea claim.

162. Regeneron presented, or caused to be presented, false or fraudulent claims with actual knowledge of their falsity, or with deliberate ignorance as to their truth or falsity, or with reckless disregard of their truth or falsity.

163. The State of North Carolina, by and through the NC Medicaid program, and unaware of Regeneron's conduct, paid the claims submitted for Eylea by healthcare providers.

164. By virtue of Regeneron's conduct, North Carolina has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each instance of unlawful conduct and the costs of this civil action.

Count VII
North Carolina False Claims Act: False Statements to Get a Claim Paid
(N.C. Gen. Stat. 1-607(a)(2)

165. North Carolina realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

166. Regeneron knowingly made or used, or caused to be made or used, a false record or statement material to a false or fraudulent claim in violation of the North Carolina False Claims

Act, N.C. Gen. Stat. § 1-607(a)(2) in that Regeneron knowingly created and submitted false and fraudulent inflated ASP reports to CMS.

167. The fraudulent ASP reports were material to, and NC Medicaid actually relied on them, in determining North Carolina Medicaid reimbursement for claims for Eylea.

168. Regeneron made or used, or caused to be made or used, false or fraudulent claims with actual knowledge of their falsity, or with deliberate ignorance as to their truth or falsity, or with reckless disregard of their truth or falsity.

169. By virtue of Regeneron's conduct, North Carolina has suffered actual damages and is entitled to recover treble damages plus civil monetary penalties for each instance of unlawful conduct and the costs of this civil action.

Count VIII
Unjust Enrichment

170. North Carolina realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

171. North Carolina is entitled to the recovery of monies by which Regeneron has been unjustly enriched due to its actions as described in this complaint.

172. By virtue of the conduct and acts described above, Regeneron was unjustly enriched at the expense of the State of North Carolina in an amount to be determined, which, under the circumstances, in equity and good conscience, and as dictated by the needs of justice and fairness, should be returned to the State of North Carolina and would be unconscionable for Regeneron to retain.

CLAIMS OF THE STATE OF TEXAS

Count IX
Making and Inducing False Statements of Material Fact to Receive an Unauthorized Payment under the Medicaid Program

(TEX. HUM. RES. CODE § 36.002(1))

173. Texas realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

174. Regeneron violated the TMFPA by knowingly making or causing to be made a false statement or misrepresentation of Eylea's ASP to receive a benefit or payment under the Texas Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized.

175. Regeneron was aware of its obligation to report ASP truthfully and accurately to CMS, in accordance with price reporting requirements.

176. Under the TMFPA's definition of "knowingly,"[30] Regeneron knew or should have known that the credit card processing fees failed to qualify as bona fide service fees; Regeneron knew or should have known its payments were price concessions that subsidized customers' Eylea purchases; and knew it was obligated to report them to CMS, and yet Regeneron knowingly, under the TMFPA's definition, failed to deduct them as price concessions in its ASP reports.

177. As a result of Regeneron reporting inflated ASP for Eylea, Regeneron committed unlawful acts when it knowingly caused to be made a false statement or misrepresentation of Eylea's ASP to receive a benefit or payment under the Texas Medicaid program that was not authorized or was greater than the benefit or payment that was authorized.

Count X
Concealing and Failing to Disclose Information that Permitted a Person to Receive an Unauthorized Payment under the Medicaid Program
(TEX. HUM. RES. CODE § 36.002(2))

178. Texas realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

[30] TEX. HUM. RES. CODE § 36.011(b).

179. As described above, Regeneron knew or should have known its payments of credit card processing fees were price concessions that subsidized customers' Eylea purchases and knowingly failed to deduct them as price concessions in its ASP reports.

180. Regeneron knew or should have known that it was legally obligated to report price concessions to CMS and that doing so would lower Eylea's ASP.

181. Regeneron committed unlawful acts when it knowingly concealed or failed to disclose its payment of credit card fees as price concessions in its ASP reports to CMS which permitted a person to receive a benefit or payment under the Texas Medicaid program that was not authorized or that was greater than the benefit or payment that was authorized.

Count XI
Making and Inducing False Statements About Information Required by Law
(TEX. HUM. RES. CODE § 36.002(4)(B))

182. Texas realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

183. Under the TMFPA's definition of "knowingly,"[31] Regeneron knew or should have known its payments of credit card processing fees were price concessions that subsidized customers' Eylea purchases and knew or should have known that federal law required it to deduct price concessions from Eylea's ASP. *See* 42 C.F.R. § 414.804(a)(2)(i) ("In calculating the manufacturer's average sales price, a manufacturer *must* deduct price concessions.") (emphasis added).

184. By virtue of the acts described above, Regeneron committed unlawful acts when it knowingly made or caused to be made a false statement or misrepresentation of Eylea's ASP when it failed to deduct price concessions from its ASP reports to CMS and knew that the resulting

[31] *See supra* note 30.

inflated ASP would be used by the State of Texas to determine the amount that the Texas Medicaid program paid for Eylea from January 1, 2013 to March 31, 2019, September 1, 2020 through February 28, 2021, and again from September 1, 2021 to present.

Civil Remedies Under the TMFPA for Texas's Counts IX-XI

185. Texas will seek an amount as civil penalties that will be justified and appropriate under the facts and the law.

186. A defendant who commits an unlawful act may not supply or sell a product under the Texas Medicaid program for ten years. *Id*. at § 36.005(b).

187. Texas invokes in the broadest sense all relief possible under the TMFPA whether specified in this pleading or not.

188. For these reasons, Texas respectfully requests this Court to enter judgment for Texas and against Regeneron for Texas's Counts IX-XI of this complaint and impose the following civil remedies and civil penalties:

A. Texas requests that judgment be entered upon trial of this case in favor of Texas and Relators against Regeneron to the maximum extent allowed by law.

B. Texas asks that it recover from Regeneron under the TMFPA:

i. The value of any payments or any monetary or in-kind benefits provided under the Texas Medicaid program, directly or indirectly, as a result of Regeneron's unlawful acts;

ii. Interest on the value in B(i);

iii. Civil penalties in an amount not less than $5,500.00 or more than $11,000.00 or the maximum amount imposed as provided by 31 U.S.C. § 3729(a), if that amount exceeds $11,000, for each unlawful act Regeneron committed;

iv. Two times the value in (B)(i); and

v. Attorneys' fees, expenses, and costs.

Id. at §§ 36.052, 36.007.

C. Texas also asks for other relief at law or in equity which it may show it is entitled to.

CLAIMS OF THE STATE OF WASHINGTON

Count XII
Medicaid Fraud False Claims Act
(Rev. Code Wash. §§ 74.66.005 *et seq*.)

189. Washington re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint in Partial Intervention.

190. This is a claim for treble damages and civil penalties under the Washington Medicaid Fraud False Claims Act, Rev. Code Wash. §§ 74.66.005 *et seq*.

191. Regeneron made misrepresentations and submitted false ASP reports to CMS, as described above. By doing this, Regeneron knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval to the Washington Medicaid Program, and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

192. Moreover, by virtue of the misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the Washington Medicaid Fraud False Claims Act.

193. The Washington Medicaid Program, unaware of the false or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

194. By reason of these payments, the Washington Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

Prayer for Relief

WHEREFORE, the undersigned Intervening States respectfully request this Court to enter judgment for Intervening States and against Defendant Regeneron on each count of this Complaint, impose damages and penalties as described above and to the full extent allowed by law and in equity and award all costs and fees as applicable under state law.

Demand for Jury Trial

The Intervening States demand a jury trial on all claims alleged herein.

Dated: June 25, 2024

Respectfully submitted,

THE STATE OF COLORADO
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