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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA; the States of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, and WASHINGTON; the DISTRICT OF COLUMBIA; *ex rel.*, EVEREST PRINCIPALS, LLC,

Plaintiff and Relator,

v.

ABBOTT LABORATORIES, ABBOTT LABORATORIES INC., ABBOTT CARDIOVASCULAR SYSTEMS INC., and ABBOTT VASCULAR INC.,

Defendants.

Case No.: 3:20-cv-00286-W-MSB

THIRD AMENDED FALSE CLAIMS ACT COMPLAINT

JURY TRIAL DEMANDED

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I. INTRODUCTION

1. Relator, Everest Principals, LLC ("Everest" or "Relator"), brings this *qui tam* action[1] seeking damages and civil penalties on behalf of the United States of America (the "United States") and the states of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, and Washington, as well as the District of Columbia (collectively, the "Plaintiff-States") pursuant to the *qui tam* provisions of the federal False Claims Act ("FCA"), 31 U.S.C. §§ 3729 *et seq.*; the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b, and applicable analogous state laws[2], against Defendants, Abbott Laboratories ("Abbott Labs"), Abbott Laboratories Inc. ("ALI"), Abbott Cardiovascular Systems Inc., ("ACS") and Abbott Vascular Inc. ("AVI") (hereinafter collectively referred to as "Abbott," "Defendants," or the "Company").

2. As set forth more fully below, Relator alleges in this action that Defendants engaged in an unlawful, systematic, and nationwide scheme of paying kickbacks to physicians and hospitals in the form of, *inter alia,* patient referrals, patient practice building, free patient marketing service, honoraria for sham speaker programs, rewards in the form of clinical trial opportunities, marketing events and consulting services, free lavish meals, and cocktail parties, to induce physicians and hospitals to use Abbott's

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[1] Relator files this Third Amended Complaint pursuant to Fed. R. Civ. P. 15(a)(2) and within the time prescribed by the Court's April 18, 2023 Order [Dkt. No. 77].

[2] Relator is not pursuing claims on behalf of the State of Maryland because the State has not elected to intervene in this action, thus, pursuant to Maryland Code, Health - General, § 2-604(a)(7), the claims are dismissed. Relator is also not pursuing claims on behalf of the Commonwealth of Massachusetts because as a corporation, Relator does not have standing to bring suit under Massachusetts False Claims Act, G. L. c. 12, §§ 5A-5O.

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MitraClip® device ("MC Device") for medical procedures performed on cardiac patients covered by Medicare, TRICARE, the Veterans Administration health care program, Medicaid, the Plaintiff-States' healthcare programs, and other state and federally-funded healthcare programs (together hereinafter referred to as "Government Healthcare Program(s)"), in violation of the FCA, AKS, and analogous state laws and statutes.

3. By paying kickbacks to doctors and hospitals, Abbott knowingly caused the submission of thousands of false claims for payment to Government Healthcare Programs. Accordingly, Abbott is liable under the FCA, AKS, and applicable analogous state laws for treble damages and penalties for these claims for payment for the Transcatheter Mitral Valve Repair ("TMVR") procedure[3], the MC Device, and hospital costs, as discussed in detail below.

4. Abbott's unlawful scheme was, and still is, widespread and ratified at the highest levels of the Company.

II. PARTIES

5. Relator is a single member Delaware limited liability corporation whose sole member was employed by Abbott from August 2015 to April 2017 as a Therapy Development Specialist in its Structural Heart Division.[4] Relator has personal knowledge and experience regarding Abbott's kickback schemes and false claims alleged herein and has information that these practices are continuing to this date. Relator brings

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[3] Pursuant to the Centers for Medicare and Medicaid Services ("CMS") National Coverage Determination ("NCD") issued on January 19, 2021, the term Transcatheter Mitral Valve Repair, or TMVR, was replaced with the term Transcatheter Edge-to-Edge Repair, or TEER, to more precisely define the treatment of functional and degenerative MR. Accordingly, procedures referenced in this Second Amended Complaint that pre-date this NCD will be referred to as TMVR, and those that post-date the NCD will be referred to as TEER.

[4]Relator and Relator's sole member are referred to hereafter collectively as "Relator." Relator was always informed that his/her employer was Abbott Labs.

1 this action on behalf of the United States and the Plaintiff-States pursuant to the *qui tam*
2 provisions of the FCA, the AKS, and applicable and analogous state laws.
3 6. Abbott Labs (NYSE:ABT) is a publicly traded, global healthcare company
4 organized under the laws of the State of Illinois and headquartered in Abbott Park,
5 Illinois. In 2009, Abbott Labs fully acquired the company that developed and holds the
6 patent for the MC Device, Evalve Inc., for $410 million dollars. Abbott Labs is the
7 corporate parent of ALI, AVI, and ACS and dictated and controlled all of the operational
8 policies and practices, including the marketing and sales policies and practices, with
9 respect to the MC Device. Abbott Labs also controls all ethics and compliance policies
10 and practices with respect to Abbott, including in connection with the implementation of
11 such policies and practices as required by Abbott's past Corporate Integrity Agreement
12 ("CIA") with the Office of Inspector General of the Department of Health and Human
13 Services ("HHS-OIG") of the United States. Abbott Labs also controls such policies and
14 practices by operating and controlling the Office of Ethics and Compliance, as well as all
15 internal investigations, of Abbott (including for ALI, AVI, and ACS).
16 7. ALI is a Delaware corporation formed in 1997 and headquartered in Abbott
17 Park, Illinois, the same location as Abbott Labs. ALI is a wholly owned subsidiary of
18 Abbott Labs. ALI manufactures and sells medicals devices, instruments, medications,
19 and other health care produces. Relator's sole member received his/her paychecks from
20 ALI.
21 8. AVI is a Delaware corporation with a principal place of business at 3200
22 Lakeside Drive, Santa Clara, California, the same business address as ACS, and presents
23 itself as the Vascular Division of Abbott Labs. AVI is a wholly owned subsidiary of
24 Abbott Labs. Relator and his/her managers received their employment agreements from
25 AVI, but, as noted above, then received their paychecks and normal compensation from
26 ALI (while receiving certain non-scheduled compensation from AVI) and were employed
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by Abbott, which functions as one enterprise.[5] AVI conducted Abbott Labs' speaker programs with respect to the MC Device ("Speaker Programs"), as well as marketed the MC Device on behalf of Abbott. AVI also provided employee training on behalf of Abbott Labs with respect to the marketing and sales of the MC Device.

9. ACS also is a subsidiary of Abbott Labs and is a corporation organized and existing under the laws of the State of California with its principal place of business at 3200 Lakeside Drive, Santa Clara, California, the same address as AVI. ACS is a wholly owned subsidiary of Abbott Labs and also is a subsidiary of AVI. ACS presents itself as the Structural Heart Division of Abbott Labs' Vascular Division (*i.e.*, AVI) and sells the MC Device under an exclusive license from another Abbott Labs' subsidiary, Evalve.

10. ACS and AVI form the structural heart and vascular businesses of Abbott Labs and, at all pertinent times, together with ALI, all four defendants functioned as a joint entity, an integrated enterprise, as alter egos of each other, as agents of each other and a single or joint employer. Abbott Labs acquired the company that owns the patent for the MC Device (Evalve), sells the MC Device through another subsidiary (ACS), and markets the MC Device through another subsidiary (AVI) whose employees are paid by ALI, who engage in the unlawful practice building and provide the illegal inducements to the physicians for referring patients to other physicians who implant the MC Devices while providing other illegal inducements to the physicians who implant the MC Devices on Abbott's behalf.

11. At all pertinent times, from a corporate perspective, Abbott Labs has paid the inducements that resulted in the false claims at issue on behalf of ALI, AVI, and ACS and has profited by selling the MC Devices to physicians and hospitals as a result of those false claims (and then made licensure payments to Evalve). Abbott Labs, however,

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[5] For example, Michael Dale, Abbott's Senior Vice President of the Structural Heart division, receives Abbott Labs (ABT) stock options as part of his compensation package.

operates on a consolidated financial basis such that the profits of ALI, ACS, AVI, and Evalve all ultimately flow up to and reside in Abbott Labs, such that it would be inequitable not to hold each of the defendants liable for the conduct at issue in this case.

12. Defendants directly participated in the false claim violations described herein and were the alter egos of one another, there being a sufficient unity of interest and ownership among and between them that the acts of one were for the mutual benefit of and can be imputed to the others. Specifically, the policies and practices that resulted in the kickbacks at issue were perpetrated and encouraged by their common management.

13. Abbott Labs filed consolidated financial statements and consolidated statements of operations of its subsidiaries with the Securities and Exchange Commission. Such consolidation was proper pursuant to Generally Accepted Accounting Principles because Abbott Labs controlled ALI, ACS, AVI and its other subsidiary entities, including Evalve. More specifically, ALI, ACS, AVI, and Evalve were mere instrumentalities or conduits through which Abbott Labs did business. It would be inequitable to treat Abbott as anything but one individual entity.

14. ALI, ACS, and AVI operate in an essentially undercapitalized manner with essentially all of their profits placed in and under the control of Abbott Labs.

15. Abbott portrays itself as a single entity, publicly promoting itself as a unified nationwide operation through brochures, marketing materials, website, and communications with the media, as well as in correspondence to state licensing and certification agencies.

16. There is and was sufficient unity of interest and ownership among and between each Defendant such that the acts of one were for the benefit of and could be imputed to all others. Further, at all times herein mentioned, each Defendant acted as the agent and partner of, conspired with, and participated in a joint venture with the remaining Defendants. Moreover, in engaging in the conduct described below,

Defendants all acted with the express or implied knowledge, consent, authorization, approval, and/or ratification of their co-defendants.

17. To the extent that any of the Defendants was not considered the alter ego of the others for purposes of the claims asserted in this Second Amended Complaint ("Complaint"), they alternatively would be liable for engaging in conspiracy to violate applicable law, as set forth below.

III. JURISDICTION AND VENUE

18. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732. This Court has supplemental jurisdiction over the counts relating to the analogous false claims act statutes of the states of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, and Washington, along with the District of Columbia, pursuant to 28 U.S.C. § 1367.

19. This Court has personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732(a) because Defendants can be found in, reside, or transact business in this District. Additionally, this Court has personal jurisdiction over Defendants because acts prohibited by 31 U.S.C. § 3729 occurred in this District.

20. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) because Defendants transact business in this District and numerous acts proscribed by 31 U.S.C. § 3729 occurred in this District.

21. Relator is the original source of the information upon which this Complaint is based and the facts alleged herein, as that phrase is used in the FCA and other laws at issue in this Complaint.

22. Relator has complied with all procedural requirements of the laws under which this case is brought.

23. Relator brings this action based on its personal knowledge and, where indicated, on information and belief. None of the actionable allegations set forth in this Complaint are based on public disclosure as set forth in or within the meaning of 31 U.S.C. § 3730(e)(4).

IV. THE REGULATORY ENVIRONMENT

A. Government Funded Healthcare Programs

i. Medicare

24. In 1965, Congress enacted the Health Insurance for the Aged and Disabled Act, 42 U.S.C. §1395, *et seq.*, known as the Medicare Program ("Medicare" or "Medicare Program"), as part of Title XVIII of the Social Security Act ("SSA"), to pay for the costs of certain health care services. Entitlement to Medicare is based on age, disability, or affliction with end-stage renal disease. *See* 42 U.S.C. §§ 426, 426-1. The regulations implementing the Medicare Program are found at 42 C.F.R. § 409, *et seq*.

25. The Secretary of Health and Human Services ("HHS") administers Medicare through the Centers for Medicare and Medicaid Services ("CMS"). The Medicare program consists of both (1) Medicare Part A, which authorizes the payment of federal funds for hospitalization and post-hospitalization care, 42 U.S.C. § 1395c-1395i-2 (1992); and (2) Medicare Part B, which authorizes the payment of federal funds for outpatient-type services, including, but not limited to, physician services, supplies and services incident to physician services, laboratory services, outpatient therapy, diagnostic services, and radiology services. 42 U.S.C. § 1395(k), (i), (s).

26. To participate in the Medicare Program, a provider of services must file a provider agreement with the Secretary of HHS. 42 U.S.C. § 1395cc. The provider certifies that he/she/it is knowledgeable of Medicare requirements on the Medicare provider enrollment form. The provider agreement requires compliance with the requirements that the HHS Secretary deems necessary for participation in the program.

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Id.

27. Medicare enters into agreements with physicians to establish the physician's eligibility to participate in the Medicare Program. For physicians to be eligible for participation in the Medicare program, they must certify that they agree to comply with the AKS, among other federal health care laws. Specifically, on the Medicare enrollment form, CMS Form 855I, the "Certification Statement" that the medical provider signs states: "You MUST sign and date the certification statement below in order to be enrolled in the Medicare program. In doing so, you are attesting to meeting and maintaining the Medicare requirements stated below." Those requirements include:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to me . . . The Medicare laws, regulations and program instructions are available through the fee-for-service contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare.
>
> * * *
>
> I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare and will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

28. Part B of the Medicare Program is funded by insurance premiums paid by enrolled Medicare beneficiaries and contributions from the federal treasury. Eligible individuals who are 65 or older or disabled may enroll in Part B to obtain benefits in return for payments of monthly premiums as established by HHS. Payments under the Medicare Program are often made directly to service providers such as physicians, rather than to the patient/beneficiary. This occurs when the provider accepts assignment of the right to payment from the beneficiary. In that case, the provider bills the Medicare Program.

29. Part B of the Medicare Program covers certain facility use and medical

services provided to qualified patients/beneficiaries, including outpatient services such as the services rendered by Defendants.

30. The United States provides reimbursement for Medicare claims from the Medicare Trust Fund through CMS. To assist in the administration of Part B of the Medicare Program, CMS contracts with Medicare Administrative Contractors ("MACs"). MACs process the reimbursement of claims for Part B services submitted by Defendants on CMS Form 1500 to Medicare.

31. CMS Form 1500 currently requires the following certification by physicians and suppliers as a pre-condition of payment:

> In submitting this claim for payment from federal funds, I certify that: 1) the information on this form is true, accurate and complete; 2) I have familiarized myself with all applicable laws, regulations, and program instructions, which are available from the Medicare contractor; 3) I have provided or will provide sufficient information required to allow the government to make an informed eligibility and payment decision; 4) this claim, whether submitted by me or on my behalf by my designated billing company, complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute and Physician Self-Referral law (commonly known as Stark law); 5) the services on this form were medically necessary and personally furnished by me or were furnished incident to my professional service by my employee under my direct supervision, except as otherwise expressly permitted by Medicare or TRICARE; 6) for each service rendered incident to my professional service, the identity (legal name and NPI, license #, or SSN) of the primary individual rendering each service is reported in the designated section. For services to be considered "incident to" a physician's professional services, 1) they must be rendered under the physician's direct supervision by his/her employee, 2) they must be an integral, although incidental part of a covered physician service, 3) they must be of kinds commonly furnished in physician's offices, and 4) the services of non-physicians must be included on the physician's bills.

32. In submitting Medicare claim forms, then, providers must certify: (1) that they are knowledgeable of Medicare requirements; (2) that the information included on the form presents an accurate description of the services rendered; and (3) that the services were medically indicated and necessary for the health of the patient.

ii. Medicaid

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33. Medicaid was also created in 1965 as part of the SSA and authorized federal grants to states for medical assistance to low-income, blind, or disabled persons, or members of families with dependent children or qualified pregnant women or children. The Medicaid program is jointly financed by the federal and state governments. CMS administers Medicaid on the federal level. The federal portion of each state's Medicaid expenditures varies by state. States pay medical providers directly, but they procure the federal share of payment from accounts which draw on the United States Treasury. 42 C.F.R. §§ 430.0-430.30 (1994).

34. The law requires state Medicaid plans to execute written agreements between the Medicaid agency and each provider furnishing services under the plan ("provider agreements"). 42 C.F.R. § 431.107(b). Providers who participate in the Medicaid program must sign provider agreements with their states that certify compliance with the state and federal Medicaid requirements, including the AKS. Although there are variations among the states, the agreement typically requires the prospective Medicaid provider to agree that he or she will comply with all state and federal laws and Medicaid regulations in billing the state Medicaid program for services or supplies furnished.

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

36. In California, for example, physicians and pharmacies must periodically sign a "California Med-Cal Provider Agreement," in which the provider certifies it will "comply with all federal laws and regulations governing and regulating Medicaid providers," and "that it shall not engage in or commit fraud and abuse" in which "'Fraud' . . . includes any act that constitutes fraud under applicable federal or state law" as a

1 "condition precedent to payment to provider."

2 37. The following states have provider certification requirements for their

3 Medicaid programs that are the same or similar to that of the State of California in all

4 material respects.

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Alabama	The Provider Enrollment application that a provider is required to sign before it can participate in the State of Alabama Program requires a provider to agree to the following: "As a condition for participation as a provider under the Alabama Medicaid Program (MEDICAID), the provider (Provider) agrees to comply with all terms and conditions of this Agreement…. "§1.1. This Agreement is deemed to include . . . all State and Federal laws and regulations. §1.2.3. This Agreement is subject to all state and federal laws and regulations relating to fraud and abuse in health care and the Medicaid program." *See* Alabama Medicaid Provider Enrollment Application, §§1.1, 1.2.3.
Alaska	The Provider Enrollment Form that a provider is required to sign before it can participate in the State of Alaska Program requires a provider to agree to the following terms and conditions: "1. To abide by federal Medicaid regulations and regulations of the Alaska Department of Health and Social Services pertaining to the furnishing of services or items or claiming payments under Alaska's Medical Assistance programs . . . . To ensure that my practice/business remains in compliance with all federal and state, laws, regulations, policies, and rules . . . ." *See* Alaska Medical Assistance Program, Provider Enrollment Form, at 4.
Arizona	The Provider Participation Agreement that a provider is required to sign before it can participate in the State of Arizona Program requires a provider to agree to the following terms and conditions:

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	"6. The Provider shall comply with all federal, State and local laws, rules, regulations, standards and executive orders governing performance of duties under this Agreement, without limitation to those designated within this Agreement…. "13. By signing this Agreement, the Provider certifies that it has not engaged in any violation of the Medicare Anti-Kickback statute (42 USC §§1320a-7b…." *See* Arizona Health Care Cost Containment System Administration Provider Participation Agreement, §111(6), (13).
Arkansas	The contract that a provider is required to sign before it can participate in the State of Arkansas Program requires a provider to agree to the following terms and conditions: "Provider, in consideration of the covenants therein, agrees: ... [t]o conform to all Medicaid requirements covered in Federal or State laws, regulations or manuals." *See* Contract to Participate in the Arkansas Medical Assistance Program, § 1(K).
California	The Provider Agreement that a provider is required to sign to participate in the State of California Program requires a provider to agree to the following: "2. Compliance With Laws and Regulations. Provider agrees to comply with all applicable provisions of Chapters 7 and 8 of the Welfare and Institutions Code (commencing with Sections 14000 and 14200), and any applicable rules or regulations promulgated by DHS pursuant to these Chapters.... Provider further agrees to comply with all federal laws and regulations governing and regulating Medicaid providers." "3. Forbidden Conduct. Provider agrees that it shall not engage in conduct inimical to the public health, morals, welfare and safety of any Medi-Cal beneficiary, or the fiscal integrity of the Medi-Cal program." "14. Provider Fraud and Abuse. Provider agrees that it shall not engage in or commit fraud and abuse. 'Fraud' . . . includes any act that constitutes fraud under applicable federal or state law." "18. Prohibition of Rebate, Refund, or Discount. Provider agrees that it shall not offer, give, furnish, or deliver any rebate, refund, commission preference, patronage dividend, discount, or any other gratuitous consideration, in connection

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	with the rendering of health care services to any Medi-Cal beneficiary. Provider further agrees that it shall not solicit, request, accept, or receive, any rebate, refund, commission preference, patronage dividend, discount, or any other gratuitous consideration in connection with the rending of health care services to any Medi-Cal beneficiary. Provider further agrees that it will not take any other action or receive any other benefit prohibited by state or federal law." "Provider agrees that compliance with the provisions of this agreement is a condition precedent to payment to provider." *See* California Medi-Cal Provider Agreement.
Colorado	The Medicaid Provider Participation Agreement that a provider is required to sign to participate in the State of Colorado Program requires a provider to agree to the following: "A. Provider will comply with all applicable provisions of the Social Security Act, as amended; federal or state laws, regulations, and guidelines; and Department rules." *See* Colorado Medicaid Provider Agreement, Definitions ¶ A.
Connecticut	The Connecticut Medical Assistance Program application that a provider is required to sign to participate in the State of Connecticut Program requires a provider to agree to the following terms and conditions: "I further certify that, if I am granted status as a provider for Connecticut Medical Assistance programs, I expressly agree to the following terms and conditions: to abide by all applicable federal and state statutes and regulations." *See* Connecticut Medical Assistance Program Enrollment/ Re-Enrollment Application. In addition, the Provider Enrollment Agreement that a provider is required to sign to participate in the State of Connecticut's Program requires a provider to agree to the following terms and conditions: "Provider . . . wishes to participate in the Connecticut Medical Assistance Program and, therefore, represents and agrees as follows:" "2. To abide by and comply with all federal and state statutes, regulations, and policies pertaining to Provider's participation in the Connecticut Medical Assistance Program."

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	"26. Provider acknowledges and understands that the prohibitions set forth in [Section 1909 of the Social Security Act] include but are not limited to.... false statements, misrepresentation, concealment, failure to disclose and conversion of benefits.... and any giving or seeking of kickbacks, rebates, or similar remuneration[.]" *See* Connecticut Department of Social Services Health Care Financing, Provider Enrollment Agreement.
Delaware	The Contract for Items or Services Delivered to Delaware's Medical Assistance Program Eligibles that a provider is required to sign in order to participate in the State of Delaware's Program requires a provider to agree to the following terms and conditions: "1. Applicable Laws and Regulations The Provider agrees, as a participant in the programs under the authority of the Delaware Medical Assistance Program (DMAP), to abide by the rules, regulations, policies and procedures of the DMAP, and to comply with all the terms, conditions, and requirements as set forth herein.... The Provider also understands that penalties may be imposed for failure to observe the terms of the Social Security Act." "3. Payment for Items or Services ... The Provider shall not solicit, charge, accept, or receive any money, gift or other consideration from a DMAP eligible or from any other person on behalf of the eligible for any service or item allowable under the DMAP...." *See* Delaware's Contract for Items or Services Delivered to Delaware Medical Assistance Program Eligibles.
District of Columbia	The Provider Agreement that a provider is required to sign to participate in the District of Columbia Program requires a provider to agree to the following: "C. To satisfy all requirements of the Social Security Act, as amended, and be in full compliance with the standards prescribed by Federal and State standards…. [and that] If the Department determines that a provider has failed to comply with the applicable Federal or District law or rule, ... the Department may do all of the following: A. Withhold all or part of the providers' payments…."

	See District of Columbia Medicaid Provider Agreement, at 20, 23.
Florida	The Medicaid Provider Agreement that a provider is required to sign to participate in the State of Florida's Program requires a provider to agree to the following: "The provider agrees to comply with local, state, and federal laws, as well as rules, regulations, and statements of policy applicable to the Medicaid program, including the Medicaid Provider Handbooks issued by [the Florida Agency for Health Care Administration]." *See* Non-Institutional Medicaid Provider Agreement. In addition, Florida's Medicaid Provider Enrollment Application, which a provider is required to sign to participate in the State of Florida's Program, requires a provider to agree that: "Providers who choose to submit claims electronically . . . must understand and agree to the following terms and conditions: . . . [a]bide by all Federal and State statutes, rules, regulations, and manuals governing the Florida Medicaid program." *See* Florida Medicaid Provider Enrollment Application.
Georgia	The Statement of Participation that a provider is required to sign to participate in the State of Georgia's Plan for Medical Assistance Program requires a provider to agree to the following terms and conditions: "2A. Legal Compliance. Provider shall comply with all of the Department's requirements applicable to the categor(ies) of service in which Provider participates under this Statement of Participation, including Part I, Part II and the applicable Part Ill manuals." "4A. Claim Submission; Certification of Claims. Provider shall submit claims for Covered Services rendered to eligible Medicaid recipients in the form and format designated by the Department. For each claim submitted by or on behalf of a Provider, Provider shall certify each claim for truth, accuracy and completeness, and shall be responsible for research and correction of all billing discrepancies without cost to the Department. This provision shall survive termination or expiration of this Statement of Participation for any reason." "4D. Reimbursement for Covered Services. Reimbursement for Covered Services performed shall be made in a form and format designated by the Department. Payment shall be made in conformity with the provisions of the Medicaid

	program, applicable federal and state laws, rules and regulations promulgated by the U.S. Department of Health and Human Services and the State of Georgia, and the Department's Policies and Procedures manuals in effect on the date the service was rendered. . . . Provider agrees that the Department shall not reimburse any claim, or portion thereof, for services rendered prior to the effective date of enrollment indicated by the Department or for which federal financial participation is not available." "Provider acknowledges that payment of claims submitted by or on behalf of Provider will be from federal and state funds, and the Department may withhold, recoup or recover payments as a result of Provider's failure to abide by the Department's requirements. This provision shall survive termination or expiration of this Statement of Participation for any reason." *See* Georgia Statement of Participation, Department of Community Health, Division of Medical Assistance, § lll (D).
Hawaii	The Hawaii State Medicaid Program Provider Agreement that a provider is required to sign to participate in the State of Hawaii's Program requires a provider to agree to the following: "1. I/We agree to abide by the applicable provisions of the Hawaii State Medicaid Program . . . and applicable provisions set forth in the Code of Federal Regulations (C.F.R.) related to the Medical Assistance Program. Upon certification by the Hawaii State Medicaid Program, I/We also agree to abide by the policies and procedures contained in the Hawaii State Medicaid Manual." "6. ... I/We am aware that it is violation of Federal law to accept or require additional payments over and beyond those established by the Hawaii State Department of Human Services for services rendered under the Hawaii State Medicaid Program." *See* Hawaii State Medicaid Program Provider Agreement and Condition of Participation, ¶ 1.
Idaho	The Provider Agreement that a provider is required to sign to participate in the State of Idaho Program requires the following: "1. Compliance. To provide services in accordance with all applicable provisions of statutes, rules and federal regulations

	governing the reimbursement of services and items under Medicaid in Idaho, including IDAPA 16.03.09 and 16.03.10, as amended; the current applicable Medicaid Provider Handbook; any Additional Terms attached hereto and hereby incorporated by reference; and any instructions contained in provider information releases or other program notices." *See* Idaho Department of Health and Human Services, Medicaid Provider Agreement.
Illinois	The Agreement for Participation in the Illinois Medical Assistance Program that a provider is required to sign to participate in the State of Illinois' Program requires a provider to agree to the following: "1. The Provider agrees, on a continuing basis, to comply with all current and future program policy and billing provisions as set forth in the applicable Department of Public Aid Medical Assistance Program rules and handbooks." "3. The Provider agrees, on a continuing basis, to comply with Federal standards specified in Title XIX and XXI of the Social Security Act and with all other applicable Federal and State laws and regulations." "6. The Provider agrees to be fully liable for the truth, accuracy and completeness of all claims submitted electronically or on hard copy to the Department for payment. Provider acknowledges that it understands the laws and handbook provisions regarding services and certifies that the services will be provided in compliance with such laws and handbook provisions. Provider further acknowledges that compliance with such laws and handbook provisions is a condition of payment for all claims submitted. Any submittal of false or fraudulent claim or claims or any concealment of a material fact may be prosecuted under applicable Federal and State laws." *See* Agreement for Participation in the Illinois Medical Assistance Program, ¶¶ 1, 3, 6.
Indiana	The Indiana Health Coverage Programs ("IHCP") Provider Agreement that a provider is required to sign to participate in the State of Indiana's Program requires a provider to agree to the following: "By execution of this Agreement, the undersigned entity ("Provider") requests enrollment as a provider in the Indiana Health Coverage Programs. As an enrolled provider in the Indiana Health Coverage Programs, the undersigned entity agrees to provide Medicaid-covered . . . services and/or supplies to Indiana Medicaid . . . members. As a condition of enrollment, this agreement cannot be altered and the Provider agrees to all of the following:..."

	"2. To comply with all federal and state statutes and regulations pertaining to the Medicaid Program or CHIP, as they may be amended from time to time." "5. To provide Medicaid-covered and CHIP-covered services and/or supplies for which federal financial participation is available for Medicaid and CHIP members pursuant to all applicable federal and state statutes and regulations." "11. To abide by the Indiana Health Coverage Programs Provider Manual [Chapter 13 of which defines Medicaid Fraud to include soliciting, offering, or receiving a kickback, bribe, or rebate]..." "13. To be individually responsible and accountable for the completion, accuracy, and validity of all claims filed under the provider number issued, including claims filed by the Provider, the Provider's employees, or the Provider's agents. Provider understands that the submission of false claims, statements, and documents or the concealment of material fact may be prosecuted under the applicable Federal and/or State law." "16. To submit claims that can be documented by Provider as being strictly for ... compensation that Provider is legally entitled to receive." *See* Indiana Health Coverage Programs ("IHCP") Provider Agreement, ¶¶ 2, 5, 11, 16(c).
Iowa	The Medicaid Provider Agreement that a provider is required to sign to participate in the State of Iowa's Program requires a provider to agree to the following: "1.4 To comply with all applicable Federal and State laws, rules and written policies of the Iowa Medicaid program, including but not limited to Title XIX of the Social Security Act (as amended), the code of Federal Regulations (CFR), the provisions of the Code of Iowa and rules of the Iowa Department of Administrative Services and written Department policies, including but not limited to, policies contained in the Iowa Medicaid Provider Manual, and the terms of this Agreement." *See* Iowa Medicaid Provider Agreement, Form 470-2965, §1.4
Kansas	The Provider Agreement that a provider is required to sign to participate in the State of Kansas Program requires a provider to agree to the following terms and conditions:

	"1. Rules, Regulations, Policies The provider agrees to participate in the Kansas Medical Assistance Program (KMAP) and to comply with all applicable requirements for participation as set forth in federal and state statutes and regulations, and Program policies, within the authorities of such statutes and regulations, of the SRS Health Care Policy (HCP) as published in the KMAP Provider Manuals and Bulletins. The provider also agrees to comply with all state and federal laws and regulations applicable to services delivered and professional activities…. 14. Fraud The provider agrees that payment of claims is from federal and/or state funds and that any false claims, statements or documents or concealment of a material fact may be prosecuted under applicable federal or state laws. The provider acknowledges that the submission of a false claim, cost report, document or other false information, charging the recipient for covered services except for authorized spenddown and co-payment, and giving or taking of a kickback or bribe in relationship to covered services are crimes which are prosecutable under applicable federal and/or state laws. Among such applicable laws is K.S.A. 21-3844 et. seq. and amendments thereto (the Kansas Medicaid Fraud Control Act)." *See* Kansas Medical Assistance Program Provider Agreement, §§ 1, 14.
Kentucky	The Provider Agreement that a provider is required to sign to participate in Kentucky's Program requires a provider to agree to the following terms and conditions: "The Provider:… (5) Assures awareness of the provisions of 42 U.S.C. § 1320a-7b . . . and of the provisions of KRS 205.8451 to KRS 205.8483 relating to Medicaid Program Fraud and Abuse…. (7) Agrees [that] . . . payment and satisfaction of claims will be from federal and state funds and that any false claims, statements, or documents or concealment or falsification of a material fact, may be prosecuted under applicable federal and state law." *See* Commonwealth of Kentucky Department for Medicaid Services Provider Agreement, §§4(5), 4(7)(c). In addition, the Provider Application that a provider is required to sign to participate in the Kentucky Program

	requires a provider to agree to the following terms and conditions: "I certify that I have read and understand the Medicaid Rules, Regulations, Policy and 42 U.S.C. § 1320a-7b ... to the best of my ability. I agree to abide by the Medicaid Program terms and conditions listed in this document…." *See* Commonwealth of Kentucky Department for Medicaid Services and/or Kentucky Health Care Partnership Provider Application, at 10.
Louisiana	The Provider Agreement Enrollment Form that a provider is required to sign to participate in the State of Louisiana Program requires a provider to agree to the following terms and conditions: "5. I agree to abide by Federal and State Medicaid laws, regulations and program instructions that are applicable to the provider type for which I am enrolled. I understand that the payment of a claim by Medicaid is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions;" "6. I agree to conduct my activities/actions in accordance with the Medical Assistance Program Integrity Law . . . as required to protect the fiscal and programmatic integrity of the medical assistance programs;" "13. I agree to adhere to the published regulations of the DHH Secretary and the Bureau of Health Services Financing, including, but not limited to, those rules regarding recoupment and disclosure requirements as specified in 42 CFR 455, Subpart B[.]" *See* Enrollment Packet for the Louisiana Medical Assistance Program (PE-50, Addendum), ¶¶ 5-6, 13.
Maine	The Provider Agreement that a provider is required to sign to participate in the State of Maine Program requires a provider to agree to the following terms and conditions: "1. Conditions of Participation. As a condition of participation or continued participation as a provider in MaineCare, the Provider agrees to comply with the provisions of the Federal and State laws and regulations related to Medicaid, the provisions of the MaineCare Benefits Manual.... 2. Changes in Federal or State laws or Regulations. a) Any change in Federal or State law or regulation that conflicts with or modifies any term of this Agreement will automatically become a part of this Agreement on the date such a change in statute or regulation becomes effective.

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	b) If the Provider objects to the application of the change in Federal or State law or regulation, it must notify the Department within thirty (30) calendar days of the effective date of the change that it will terminate the Agreement…. Failure to so notify the Department will be deemed acceptance of the change in law or regulation as part of this Agreement…. 5. Certification…. b) The Provider ... certifies that at the time that this Agreement is executed neither it nor any of its employees, group members or agents has engaged in any activities prohibited by 42 U.S.C. § 1320a-7b…. d) The Provider understands that engaging in activities prohibited by 42 U.S.C. § 1320a-7b may result in sanctions or termination of this Agreement, in accordance with applicable Federal and State laws and regulations." *See* MaineCare/Medicaid Provider Agreement at A(l), (2), (5).
Maryland	The Provider Agreement that a provider is required to sign to participate in the State of Maryland Program requires a provider to agree to the following terms and conditions: "The Provider complies with all standards of practice, professional standards, levels of Service, and all applicable federal and state laws, statutes, rules and regulations, as well as all administrative policies, procedures, transmittals, and guidelines issued by the Department, including but not limited to, verifying Recipient eligibility, obtaining prior authorizations, submitting accurate, complete and timely claims, and conducting business in such a way the Recipient retains freedom of choice of providers." Maryland Medical Assistance Provider Agreement at § I.A.
Massachusetts	The Provider Agreement that a provider is required to sign to participate in the Commonwealth of Massachusetts Program requires a provider to agree to the following terms and conditions: "The Provider agrees . . . [t]o comply with all federal and state laws, regulations, and rules applicable to the Provider's participation in MassHealth, now existing or adopted during the term of this Provider Contract." *See* MassHealth Provider Agreement ¶ II. B.

Michigan	The Provider Agreement that a provider is required to sign to participate in the State of Michigan Program requires a provider to agree to the following terms and conditions: "In applying for enrollment as a provider or trading partner in the Medical Assistance Program (and programs for which the Michigan Department of Community Health (MDCH) is the fiscal intermediary), I represent and certify as follows. . . 6. Before billing for any medical services I render, I will read the Medicaid Provider Manual from the Michigan Department of Community Health (MDCH). I also agree to comply with 1) the terms and conditions of participation noted in the manual, and 2) MDCH's policies and procedures for the Medical Assistance Program contained in the manual, provider bulletins and other program notifications. 7. I agree to comply with the provisions of 42 CFR 455.104, 42 CFR 455.105, 42 CFR 431.107 and Act No. 280 of the Public Acts of 1939, as amended, which state the conditions and requirements under which participation in the Medical Assistance Program is allowed. 13. I agree to comply with all policies and procedures of the Medical Assistance Program when billing for services rendered. In pertinent part, the Michigan Medicaid Provider Manual states: "8.2 RENDERING SERVICES "All such services [Medicaid] rendered must be in compliance with the provider enrollment agreement; contracts (when appropriate); Medicaid policies; and applicable county, state, and federal laws and regulations governing the delivery of health care services." *See* Michigan Department of Health and Human Services, Medicaid Provider Manual.
Minnesota	The Provider Agreement that a provider is required to sign to participate in the State of Minnesota Program requires a provider to agree to the following: "[T]he Provider agrees to . . . [c]omply with all federal and state statutes and rules relating to the delivery of services to Individuals and to the submission of claims for such services." *See* Minnesota Health Care Programs Provider Agreement, ¶ 2.

Mississippi	The Participation Agreement that a provider is required to sign to participate in the State of Mississippi Program requires a provider to agree to the following: "The Medicaid Provider agrees ... [t]o abide by federal and state laws and regulations affecting delivery of services." *See* Mississippi Medicaid Assistance Participation Agreement § C,1]2.104
Missouri	The Participation Agreement that a provider is required to sign to participate in the State of Missouri Program requires a provider to agree to the following terms and conditions: "1. [Provider] will comply with the Medicaid manual, bulletins, rules and regulations as required by the Division of Medical Services and the United States Department of Health and Human Services in the delivery of services and merchandise and in submitting claims for payment. I understand that in my field of participation I am not entitled to Medicaid reimbursement if I fail to so comply, and that I can be terminated from the program for failure to comply…. 117. Medicaid participation under this agreement may be terminated...Such reason(s) could include the provider being in violation of . . . (c) rules regulations, policies or procedures of the Division of Medical Services. . . . The provider must be in compliance with all other applicable state or federal laws or regulations. Violation of any law or regulation may result in this agreement being terminated immediately upon mailing of written notice from the Division of Medical Services…. *See* Missouri Department of Social Services, Division of Medical Services Participation Agreement, 1, 7.
Montana	The Provider Agreement that a provider is required to sign to participate in the State of Montana Program requires a provider to agree to the following terms and conditions: "The Provider hereby agrees to comply with all applicable laws, rules and written policies pertaining to the Montana Medicaid Program (Medicaid), including but not limited to Title XIX of the Social Security Act, the Code of Federal Regulations (CFR), Montana Codes Annotated (MCA), Administrative Rules of Montana (ARM) and written Department of Public Health and Human Services (Department) policies, including but not limited to policies contained in the Medicaid provider manuals, and the terms of this document." *See* Montana Medicaid Provider Enrollment Agreement and Signature Page, at 2.

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Nebraska	The Provider Agreement that a provider is required to sign to participate in the State of Nebraska's Program requires a provider to agree to the following terms and conditions: "I agree to participate as a provider in the Nebraska Medical Assistance Program, and assure the Nebraska Health and Human Services System: • That the policies and procedures of the Nebraska Health and Human Services System in the administration of the Nebraska Medical Assistance Program will be followed…. • That any false claims (including claims submitted electronically), statements, documents, or concealment of material fact may be prosecuted under applicable State or Federal laws (42 CFR 455.18)…. I certify the information on this form is true, accurate, and complete." *See* Medical Assistance Provider Agreement, at 2.111. The policies and procedures of the Nebraska Medical Assistance Program include the following: "2-001.03 Provider Agreements: Each provider is required to have an approved agreement with the Department. By signing the agreement, the provider agrees to – 1. Fully meet standards established by the federal Department of Health and Human Services, and any applicable state and federal laws governing the provision of their services.... *See* Nebraska HHS Finance and Support Manual, Chapter 2-000 Provider Participation, at 1.
Nevada	The Provider Application that a provider is required to sign to participate in the State of Nevada Program requires a provider to agree to the following terms and conditions: "I understand that I am responsible for the presentation of true, accurate and complete information on all invoices submitted to First Health Services. I further understand that payment and satisfaction of these claims will be from federal and state funds and that false claims, statements, documents, or concealment of material facts may be prosecuted under applicable federal and state laws." *See* Provider Enrollment Application, at 6.
New Jersey	The Provider Agreement that a provider is required to sign to participate in the State of New Jersey Program requires a provider to agree to the following terms and conditions:

	"Provider agrees: (1) To comply with all applicable State and Federal laws, policies, rules and regulations...."
New Mexico	The Provider Agreement that a provider is required to sign to participate in the State of New Mexico Program requires a provider to agree to the following terms and conditions: The "Medicaid Provider Shall: 1.1 Abide by all federal, state, and local laws, rules, and regulations, including but not limited to those laws, regulations, and policies applicable to providers of medical services under Title XIX (Medicaid) and Title XXI (SCHIP) of the Social Security Act and other health care programs administered by HSD." "1.11 Submission of false claims or fraudulent representation may subject the provider to termination, criminal investigation and charges, and other sanctions specified in the MAD Provider Program Manual." "7.3 Provider status may be terminated immediately, without notice, in instances in which the health and safety of clients in institutions are deemed to be in immediate jeopardy; are subject to an immediate or serious threat; or when it has been demonstrated, on the basis of reliable evidence, that a provider has committed fraud, abuse[.)" "BY SIGNATURE, THE PROVIDER AGREES TO ABIDE BY AND BE HELD TO All FEDERAL. STATE, AND LOCAL LAWS, RULES, AND REGULATIONS, INCLUDING, BUT NOT LIMITED TO THOSE APPLICABLE TO MEDICAID AND THOSE STATED HEREIN. BY SIGNATURE, THE PROVIDER SOLEMNLY SWEARS UNDER PENALTY OF PERJURY THAT THE INFORMATION GIVEN IS TRUE AND ACCURATE." *See* New Mexico Provider Participation Agreement, at 3-6.
New York	The Provider Certification that a provider is required to sign to participate in the State of New York Program also requires a provider to agree to the following terms and conditions: "As of [date of the certification], all claims submitted electronically or on paper to the State's Medicaid fiscal agent . . . will be subject to the following certification...."

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	"I (or the entity) have furnished or caused to be furnished the care, services, and supplies itemized and done so in accordance with applicable federal and state laws and regulations...." "All statements, data and information transmitted are true, accurate and complete to the best of my knowledge; no material fact has been omitted; I understand that payment and satisfaction of this claim will be from federal, state and local public funds and that I may be prosecuted under applicable federal and state laws for any violation of the terms of this certification including but not limited to false claims, statements or documents, or concealment of a material fact...." "In submitting claims under this agreement I understand and agree that I (or the entity) shall be subject to and bound by all rules, regulations, policies, standards, fee codes and procedures of the New York State Department of Health and the Office of the Medicaid Inspector General as set forth in statute or title 18 of the Official Compilation of Codes, Rules and Regulation of New York State and other publications of the Department, including eMed NY Provider Manuals and other official bulletins of the Department." *See* New York Certification Statement for Provider Billing Medicaid.
North Carolina	The Provider Agreement that a provider is required to sign to participate in the State of North Carolina Program requires a provider to agree to the following terms and conditions: "A .1. Comply with federal and state laws, regulations, state reimbursement plan and policies governing the services authorized under the Medicaid Program and this agreement (including, but not limited to, Medicaid provider manuals and Medicaid bulletins published by the Division of Medical Assistance and/or its fiscal agent)." "B.1. Payment of claims is from State, Federal and County funds and any false claims, false statements or documents, or misrepresentation or concealment of material fact may be prosecuted by applicable State and/or Federal law." "C.6. To not offer or provide any discount, rebate, refund, or any other similar unearned gratuity for the purpose of soliciting the patronage of Medicaid clients." *See* North Carolina Division of Medical Assistance Medicaid Participation Agreement, at 3-5.131.

	In addition, North Carolina's Electronic Claims Submission (ESA) Agreement states: "The Provider of Medical Care ("Provider") under the Medicaid Program in consideration of the right to submit claims by paperless means rather than by, or in addition to, the submission of paper claims agrees that it will abide by the following terms and conditions: 1. The Provider shall abide by all Federal and State statutes, rules, regulations and policies (including, but not limited to: the Medicaid State Plan, Medicaid Manuals, and Medicaid bulletins published by the Division of Medical Assistance (OMA) and/or its fiscal agent of the Medicaid Program, and the conditions set out in any Provider Participation Agreement entered into by and between the Provider and OMA. 2. Provider's signature electing electronic filing shall be binding as certification of Provider's intent to file electronically and its compliance with all applicable statutes, rules, regulations and policies governing electronic claims submission. The Provider agrees to be responsible for research and correction of all billing discrepancies. Any false statement, claim or concealment of or failure to disclose a material fact may be prosecuted under applicable federal and/or state law (P.L. 95-142 and N.C.G.S. 108A-63), and such violations are punishable by fine, imprisonment and/or civil penalties as provided by law. 5. . . . For purposes of compliance with this agreement and the laws, rules, regulations and policies applicable to Medicaid providers, the acts and/or omissions of Provider's staff or any entity acting on its behalf for electronic submission of the Provider's claims shall be deemed those of the Provider, including any acts and/or omissions in violation of Federal and State criminal and civil false claims statutes . . . . The undersigned having read this Agreement for billing Medicaid claims electronically and understanding it in its entirety, hereby agree(s) to all of the stipulations, conditions, and terms stated herein." *See* North Carolina Department of Health and Human Services Division of Medical Assistance Electronic Claims Submission (ECS) Agreement, at 1-3. It further states: "By signature below, I understand and agree that non-electronic Medicaid claims may be submitted without

	signature and this certification is binding upon me for my actions as a Medicaid provider, my employees, or agents who provide services to Medicaid recipients under my direction or who file claims under my provider name and identification number. I certify that all claims made for Medicaid payment shall be true, accurate, and complete and that services billed to the Medicaid Program shall be personally furnished by me, my employees, or persons with whom I have contracted to render services, under my personal direction. I understand that payment of claims will be from federal, state and local tax funds and any false claims, statements, or documents or concealment of a material fact may be prosecuted under applicable Federal and State laws and I may be fined or imprisoned as provided by law." *See* North Carolina Division of Medical Assistance, Provider Certification for Signature on File.
Ohio	The Provider Agreement that a provider is required to sign to participate in the State of Ohio Program requires a provider to agree to the following terms and conditions: "This provider agreement is a contract between the Ohio Department of Job and Family Services (the Department) and the undersigned provider of medical assistance services in which the Provider agrees to comply with the terms of this provider agreement, state statutes, Ohio Administrative Code rules, and Federal statutes and rules...." *See* Ohio Health Plans Provider Enrollment Application/Agreement at 13.
Oklahoma	The Provider Agreement that a provider is required to sign to participate in the State of Oklahoma Program requires a provider to agree to the following terms and conditions: "4.1 (c) Provider agrees to comply with all applicable Medicaid statutes, regulations, policies, and properly promulgated rules of OHCA...." "4.2 (e) Satisfaction of all claims will be from federal and state funds. Any false claims, statements, or documents, or any concealment of a material fact may be prosecuted under applicable federal or state laws." "5.0 The parties to this Agreement acknowledge and expect that over the term of this Agreement laws may change. Specifically, the parties acknowledge and expect (i) federal Medicaid statutes and regulations, (ii) state Medicaid statutes and rules, (iii) state statutes and rules governing practice of

	health-care professions, and (iv) any other laws cited in this contract may change. The parties shall be mutually bound by such changes." "5.2 Provider shall comply with and certifies compliance with: . . . p) The Federal False Claims Act, 31 U.S.C. § 3729-3733; 31 U.S.C. 3801." *See* Oklahoma Health Care Authority Agreement.
Oregon	The Provider Agreement that a provider is required to sign to participate in the State of Oregon Program requires a provider to agree to the following terms and conditions: "D. Compliance with applicable laws… Provider shall comply with federal, state and local laws and regulations applicable to this Enrollment Agreement, including but not limited to OAR 410-120-1380. OMAP's obligations under this Enrollment Agreement are conditioned upon Provider's compliance with provisions of ORS 279.312,279.314, 279.316, 279.320, and 279.555, as amended from time to time, which are incorporated in this agreement. Provider is responsible for all Social Security payments and federal or state taxes applicable to payments under this Enrollment Agreement." *See* OMAP Provider Application, § D.
Pennsylvania	The Provider Agreement that a provider is required to sign to participate in the Commonwealth of Pennsylvania Program requires a provider to agree to the following terms and conditions: "A. The Provider agrees to participate in the Pennsylvania Medical Assistance Program (the 'Program'), and in the course of such participation to comply with all federal and Pennsylvania laws generally and specifically governing participation in the Program. The foregoing include but are not limited to: 42 U.S.C. § 1396 *et seq*., 62 P.S.§§ 441-451,42 C.F.R. §§431-481 and the regulations adopted by the Department of Public Welfare (the 'Department'). The Provider agrees to be knowledgeable of and to comply with applicable rules, regulations, rates and fee schedules promulgated under such laws and any amendments thereto." *See* Pennsylvania Provider Agreement, § 1(A).
Rhode Island	The Provider Agreement that a provider is required to sign to participate in the State of Rhode Island Program requires a provider to agree to the following terms and conditions:

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	"I, the Provider with the understanding that participation in the Rhode Island Executive Office of Health and Human Services Medical Assistance Program hereafter, "EOHHS" or "RIMAP" is voluntary, agrees to the following: 1. To follow all laws, rules, regulations, certification standards, policies and amendments including but not limited to the False Claims Act and HIPPA, that govern the Rhode Island Medical Assistance Program as specified by the Federal Government and the State of Rhode Island. Suspected violations must be ·reported by the Provider to EOHHS, its fiscal agent, or the Medicaid Fraud Control Unit of the Rhode Island Attorney General's Office." *See* Rhode Island Executive Office of Health and Human Services Provider Agreement Form, at 1.
South Carolina	The Medicaid Enrollment form that a provider is required to sign to participate in the State of South Carolina Program requires a provider to agree to the following terms and conditions: "• That all services rendered and claims submitted shall be in compliance with all applicable federal and state laws and regulations and in accordance with SCDHHS policies, procedures and Medicaid Provider Manuals. • That all information provided on the Medicaid enrollment form is incorporated as part of this agreement. • That Medicaid reimbursement (payment of claims) is from state and federal funds and that any falsification (false claims, statement or documents) or concealment of material fact may be prosecuted under applicable state and federal laws." *See* South Carolina Medicaid Enrollment Agreement at 1-2. In addition, in 2010, the State of Carolina added the following additional term and condition: "I agree to abide by the Medicaid laws, regulations and program instructions that that apply to me or to the organization. The Medicaid laws, regulations, and program instructions are available through SCDHHS. I understand that payment of a claim by Medicaid is conditioned upon the claim and the underlying transaction complying with such laws, regulations and program instructions, and on the provider's compliance with all applicable conditions of participation in Medicaid." *See* South Carolina Medicaid Enrollment Agreement, at 1-2.
Tennessee	One of the Provider Agreements that a provider was required to sign to participate in the State of Tennessee Program

	requires a provider to agree to the following terms and conditions: "C. TENNCARE Provider Agreement Requirements… 42. The Provider, Subcontractor or any other entity agrees to abide by the Medicaid laws, regulations, and program instructions that apply to the Provider. The Provider, Subcontractor or any other entity understands that payment of a claim by TENNCARE or a TENNCARE Managed Care Contractor and/or Organization is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, federal anti-kickback statute, the Stark law, and federal requirements on disclosure, debarment and exclusion screening), and is conditioned on the Provider's, Subcontractor's, or any other entity's compliance with all applicable conditions of participation in Medicaid. The Provider, Subcontractor, or any other entity understands and agrees that each claim the Provider, Subcontractor, or any other entity submits to TENNCARE or a TENNCARE managed contractor, and/or Organization constitutes a certification that the Provider, Subcontractor, or any other entity has complied with all applicable Medicaid laws, regulations and program instructions (including, but not limited to, the federal anti-kickback statute and the Stark law and federal requirements on disclosure, debarment and exclusion screening), in connection with such claims and the services provided therein." *See* Tennessee Volunteer State Health Plan Provider Administration Manual, XII (C), ¶ 42.
Texas	The Provider Agreement that a provider is required to sign to participate in the State of Texas Program requires a provider to agree to the following terms and conditions: "As a condition for participation as a provider under the Texas Medical Assistance Program (Medicaid), the provider (Provider) agrees to comply with all terms and conditions of this agreement. I. ALL PROVIDERS 1.1 Agreement and documents constituting Agreement. Provider has a duty to become educated and knowledgeable with the contents and procedures contained in the Provider Manual. Provider agrees to comply with all of the requirements of the Provider Manual, as well as all state and federal laws governing or regulating Medicaid, and provider further acknowledges and agrees that the provider is responsible for ensuring that all employees and agents of the provider also comply. Provider agrees to acknowledge HHSC's provision of enrollment processes and authority to

	make enrollment decisions as found in Title 1, Part 15, Chapter 352 of the Texas Administrative Code. Provider is specifically responsible for ensuring that the provider and all employees and agents of the Provider comply with the requirements of Title 1, Part 5, Chapter 371 of the Texas Administrative Code, related to waste, abuse and fraud, and provider acknowledges and agrees that the provider and its principals will be held responsible for violations of this agreement through any acts or omissions of the provider, its employees, and its agents." "1.2.3. This Agreement is subject to all state and federal laws and regulations relating to fraud, abuse and waste in health care and the Medicaid program." "XI ACKNOWLEDGMENTS AND CERTIFICATIONS 11.1 By signing below, Provider acknowledges and certifies to all of the following... (g) Provider agrees to abide by all Medicaid regulations, program instructions, and Title XIX of the Social Security Act. The Medicaid laws, regulations, and program instruction are available through the Medicaid contractor. Provider understands that payment of a claim by Medicaid is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the provider's compliance with all applicable conditions of participation in Medicaid."
Virginia	The Provider Agreement that a provider is required to sign to participate in the Commonwealth of Virginia Program requires a provider to agree to the following terms and conditions: "8. The provider agrees to comply with all applicable state and federal laws, as well as administrative policies and procedures of VMAP as from time to time amended." *See* Commonwealth of Virginia Department of Medical Assistance Services Medical Assistance Program Participation Agreement, at 1.
Washington	The Provider Agreement that a provider is required to sign to participate in the State of Washington Program requires a provider to agree to the following terms and conditions: "The Provider is subject to and shall comply with all federal and state laws, rules, and regulations and all program policy provisions, including department numbered memoranda,

	billing instructions, and other associated written department issuances in effect at the time the service is rendered, which are incorporated into this Agreement by this reference." *See* Washington Core Provider Agreement (DSHS 09-048), ¶ 1.
West Virginia	The Provider Enrollment Application that a provider is required to sign to participate in the State of West Virginia Program requires a provider to agree to the following terms and conditions: "1. The Provider hereby agrees to comply with all applicable laws, rules and written policies pertaining to the West Virginia Medicaid Program (Medicaid), including but not limited to Title XIX and Title XXI (Children's Health Insurance) of the Social Security Act, the Code of Federal Regulations, the West Virginia State Plan, the Department of Health and Human Resources Bureau for Medical Services (Department/Bureau), written manuals, program instructions, policies and this document…. I understand that payment of any claims will be from Federal and State funds, and that any falsification, or concealment of a material fact may be prosecuted under Federal and State laws." *See* West Virginia Medicaid Provider Enrollment Agreement.

iii. TRICARE

38. TRICARE (formerly known as CHAMPUS) is part of the United States military's health care system, designed to maintain the health of active-duty service personnel, provide health care during military operations, and offer health care to non-active duty beneficiaries, including dependents of active duty personnel, and military retirees and their dependents. The military health system, which is administered by the Department of Defense ("DOD"), is composed of the direct care system, consisting of military hospitals and military clinics, and the benefit program known as TRICARE. TRICARE is a triple-option benefit program designed to give beneficiaries a choice

between health maintenance organizations, preferred provider organizations, and fee-for-service benefits.

39. While some physicians enroll in the TRICARE program as network or participating providers, any physician that is licensed, accredited, and meets other standards of the medical community is authorized to provide services to TRICARE beneficiaries. Physicians who are enrolled in the TRICARE network must expressly certify their compliance with TRICARE's regulations and all providers that offer services to TRICARE beneficiaries, whether network providers or non-participating providers, are required to comply with TRICARE's program requirements, including its anti-abuse provisions. 32 C.F.R. §199.9(a)(4).

40. TRICARE's Reimbursement Manual (6010.58-M, February 1, 2008) provides the following with respect to the "Reimbursement Of Covered Services Provided By Individual Health Care Professionals And Other Non-Institutional Health Care Providers":

> Services provided by individual professional providers of care and other non-institutional health care providers are to be billed only on the CMS 1500 Claim Form or the TRICARE 2642 for payment. Individual health care professionals (e.g., physicians) and non-institutional providers (e.g., suppliers) are to use the CMS 1500 Claim Form. Institutional providers (e.g., hospitals) are to use the CMS 1500 Claim Form or the CMS 1450 UB-04 (if adequate Common Procedure Terminology (CPT) coding information is submitted) to bill for the professional component of physicians and other authorized professional providers. Beneficiaries (or their representatives) who complete and file their own claims for individual health care professional and other non-institutional health care provider services may want to use the TRICARE 2642 claim form for payment.

See Chapter 1, Section 7 at 3.1.3.

41. TRICARE regulations provide that claim submitted in violation of TRICARE's anti-abuse provisions can be denied. 32 C.F.R. §199.9(b). Kickback arrangements are included within the definition of abusive situations that constitute program fraud. *Id.* §§199.2(b), 199.9(c)(12). Likewise, TRICARE's program

regulations specifically specify that providers "have a duty to familiarize themselves with, and comply with, the program requirements," while contractors and peer review organizations "have a responsibility to apply provisions of this regulation in the discharge of their duties, and to report all known situations involving fraud, abuse, or conflict of interest." *Id.* §§199.9(a)(4), (5).

42. The regulations of TRICARE and its predecessor, CHAMPUS, have established at all pertinent times that claims tainted by kickbacks are presumed to be fraudulent in nature and, as a result, should not be submitted by providers for reimbursement.

43. CMS-1500 currently requires the following certification by physicians and Suppliers as a pre-condition of payment:

> In submitting this claim for payment from federal funds, I certify that: 1) the information on this form is true, accurate and complete; 2) I have familiarized myself with all applicable laws, regulations, and program instructions, which are available from the Medicare contractor; 3) I have provided or will provide sufficient information required to allow the government to make an informed eligibility and payment decision; 4) this claim, whether submitted by me or on my behalf by my designated billing company, complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute and Physician Self-Referral law (commonly known as Stark law); 5) the services on this form were medically necessary and personally furnished by me or were furnished incident to my professional service by my employee under my direct supervision, except as otherwise expressly permitted by Medicare or TRICARE; 6) for each service rendered incident to my professional service, the identity (legal name and NPI, license #, or SSN) of the primary individual rendering each service is reported in the designated section. For services to be considered "incident to" a physician's professional services, 1) they must be rendered under the physician's direct supervision by his/her employee, 2) they must be an integral, although incidental part of a covered physician service, 3) they must be of kinds commonly furnished in physician's offices, and 4) the services of non-physicians must be included on the physician's bills.
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> For TRICARE claims, I further certify that I (or any employee) who rendered services am not an active duty member of the Uniformed Services or a civilian employee of the United States Government or a contract employee of the United States Government, either civilian or military (refer to 5 USC 5536). For Black-Lung claims, I further certify that the services

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performed were for a Black-Lung related disorder. No Part B Medicare benefits may be paid unless this form is received as required by existing law and regulations (42 CFR 424.32).

NOTICE: Anyone who misrepresents or falsifies essential information to receive payment from Federal funds requested by this form may upon conviction be subject to fine and imprisonment under applicable Federal laws.

See CMS Form 1500 at 2 (02/12).[6]

44. Various other federally-funded medical programs exist to help certain populations of eligible individuals obtain care, including the Veterans Administration, among others. The Department of Veterans Affairs ("VA") maintains a system of medical facilities from which medical devices, including the MC Device, are procured directly by the VA. The VA also reimburses certain covered individuals for medical expenses incurred in having the MC Device implanted. Medical device manufacturers such as Abbott are required to enter into national contracts with the VA, pursuant to which the manufacturer makes available for procurement the medical devices at a prescribed price. Upon information and belief, the VA awarded Abbott a contract that requires Abbott to comply with all applicable federal, state and local laws, executive orders, rules and regulations applicable to performance of Abbott's duties under that VA contract

45. Reimbursement practices under all federally-funded healthcare programs closely align with the rules and regulations governing Medicare reimbursement.

[6] Medicare and other Government Healthcare Programs began accepting Form CMS-1500 (02/12) on January 6, 2014, and fully replaced the prior Form CMS-1500 (08/05) on April 1, 2014. Express certification claims are only asserted in this Complaint in connection with the submission of Form CMS-1500 (02/12).

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iv. Government Reimbursement for Abbott's MC Device

46. Medicare beneficiaries receive the MC Device through the TMVR procedure under Medicare Part A for inpatient hospital services and Medicare Part B for physician services. The MC Device is purchased in bulk by hospitals, which then seek reimbursement for the device from the Government. Medicare reimburses the hospitals separately for the procedure to insert the device (TMVR) through a DRG Code and reimburses the implanting doctors who perform the procedure through a CPT Code. In addition, hospitals submit claims to Government Healthcare Programs for the inpatient costs associated with the procedure, on interim claim forms called Forms CMS-1450, and then on the final annual Hospital Cost Report (Form CMS-2552). The physicians performing the TMVR procedure separately bill for their professional services on Form CMS-1500, identifying the procedure by the appropriate CPT code. The Plaintiff-States also reimburse physicians and hospitals for the MitraClip implanting procedure under CPT Codes 33418 and 33419. The total estimated payments made by the Plaintiff-States' Medicaid healthcare programs to physicians and hospitals for the TMVR procedure from November 2013 until December 2020 is approximately $1.6 million dollars.

47. The DRG and CPT codes for the TMVR procedure and MC Device were modified from 2014-2017, and the Government reimbursement amounts for the procedures and device have increased. According to Abbott's 2017 Hospital Coding and Payment Guide, for the period from October 1, 2016, through September 30, 2017, hospitals billed Medicare $42,262.00 under the DRG code 228 for ***each*** MC Device procedure with major complications and comorbidities, and $28,302.00 under DRG code 229 for ***each*** MC Device procedure without such complications. During the same time frame, physicians billed Medicare $1,881.00 under CPT code 33418 for the first MC Device implanted in the patient, an additional $445.00 under code 33419 for each additional MC Device implanted during the same procedure, and $232.00 for patient

intra-procedural monitoring.[7] Thus, according to Abbott's own figures, ***each*** TMVR procedure during this period was estimated to cost Medicare ***at least*** $30,183.00 ***per patient*** for a procedure without complications, and $44,143.99 ***per patient*** for a procedure with complications. In 2018, hospitals billed Medicare close to $40,000.00 for each procedure with major complications, and this rate increased to nearly $47,000.00 one year later in 2019. In 2020, a new DRG code was assigned, and the base reimbursement payment increased to $52,000.00. For this same three-year period (2018-2020), physicians were reimbursed an average of nearly $2,000.00 for the TMVR procedure under CPT Code 33418.

V. APPLICABLE LAW

A. FEDERAL LAW

1) The False Claims Act, 31 U.S.C. § 3729, *et seq.*

48. The federal FCA provides, in pertinent part, that any person who:

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or]
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> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
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> ... is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-4101), plus 3 times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729(a)(1).

48. For purposes of the FCA, the terms "knowing" and "knowingly" are defined to mean "that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or

[7] Abbott's 2017 MitraClip© Physician Coding and Payment Guide.

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(3) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A)(i)-(iii). No proof of specific intent to defraud is required. 31 U.S.C. § 3729(b)(1)(B). The FCA defines the term "claim" in pertinent part, as:

> any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that (i) is presented to an officer, employee, or agent of the United States; or (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government-- (I) provides or has provided any portion of the money or property requested or demanded; or (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded[.]

Id. at § 3729(b)(2).

49. For purposes of the FCA, the term "material" means "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." *Id.* at § 3729(b)(4). Additionally, "[a] defendant can have 'actual knowledge' that a condition is material without the Government expressly calling it a condition of payment." *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2001–02, 198 L. Ed. 2d 348 (2015).

2) The Anti-Kickback Statute, 42 U.S.C. § 1320a, *et seq.*

50. The AKS arose out of Congressional concern that payments to those who can influence healthcare decisions would result in goods and services being provided that are medically unnecessary, excessively costly, of poor quality, or potentially harmful to patients. To protect the integrity of federal healthcare programs from these difficult-to-detect harms, Congress enacted a *per se* prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback actually gave rise to overutilization or poor quality of care. In particular, when determining what conduct to prohibit, Congress determined that the inducements at issue would "contribute significantly to the cost" of federal health care programs absent federal penalties as a

deterrent. H.R. Rep. No. 95-393, at 53 (1977), *reprinted in* 1977 U.S.C.C.A.N. 3039, 3056.

51. The AKS was first enacted in 1972, and was strengthened in 1977, 1987, and 2010, to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, §§242(b) and (c); Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93; and the Patient Protection and Affordable Care Act ("PPACA"), Pub. L. No. 111-148. In adopting and strengthening the AKS repeatedly, Congress sought to "strengthen the capability of the Government to detect, prosecute, and punish fraudulent activities under the [M]edicare and [M]edicaid programs." H.R. Rep. No. 95-393, at 1 (1977).

52. The AKS is a criminal statute that forbids, *inter alia*, any person or entity from knowingly and willfully offering, paying, soliciting, or receiving any remuneration to influence either the referral or the arrangement of services or medical goods, including medical devices that are reimbursable by a federal healthcare program. 42 U.S.C. § 1320a-7b (b). Violation of the AKS is a felony and can subject the perpetrator to criminal penalties, exclusion from participation in federal healthcare programs, and civil monetary penalties. 42 U.S.C. §1320a-7b(b)(2); 42 U.S.C. §1320a-7b(b)(7); 42 U.S.C. §1320a-7a(a)(7). In pertinent part, the AKS provides:

> (b) Illegal remunerations . . .
>
> > (2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person-
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> > (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program,

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> or
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> (B) to purchase, lease, order or arrange for or recommend purchasing, leasing or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than l0 years, or both.

42 U.S.C. §1320a-7b(b)(2).

53. The AKS defines remuneration to include anything of value, including "cash" and "in-kind" payments or rebates. 42 U.S.C. §1320a-7b(b)(2). Courts have broadly interpreted "remuneration" to mean "anything of value." *U.S. ex rel. McDonough v. Symphony Diagnostic Servs., Inc.*, 36 F. Supp. 3d 773, 777 (S.D. Ohio 2014) (quoting *Klaczak v. Consol. Med. Transp*., 458 F. Supp. 2d 622 (N.D. Ill. 2006)); *see also Hanlester Network v. Shalala*, 51 F.3d 1390, 1398 (9th Cir. 1995) ("Congress introduced the broad term 'remuneration' . . . to clarify the types of financial arrangements and conduct to be classified as illegal under Medicare and Medicaid. The phrase 'any remuneration' was intended to broaden the reach of the law which previously referred only to kickbacks, bribes, and rebates.") (citation omitted); Medicare & State Health Care Programs: Fraud & Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952-01, 35958 (July 29, 1991) (codified at 42 C.F.R. pt. 1001) ("Congress's intent in placing the term 'remuneration' in the statute in 1977 was to cover the transferring of anything of value in any form or manner whatsoever.").

54. Moreover, the AKS covers "***any arrangement where one purpose*** of the remuneration was to obtain money for the referral of services or to induce further referrals." *U.S. ex rel. Westmoreland v. Amgen, Inc*., 812 F. Supp. 2d 39, 47 (D. Mass. 2011) (citing *United States v. Greber*, 760 F.2d 68, 69 (3d Cir. 1985)) (emphasis added); *see also United States v. Narco Freedom, Inc*., 95 F. Supp. 3d 747, 759 (S.D.N.Y. 2015);

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United States v. Borrasi, 639 F.3d 774, 781-82 (7th Cir. 2011); *United States v. LaHue*, 261 F.3d 993, 1002-04 (10th Cir. 2001); *United States v. McClatchey*, 217 F.3d 823, 834-35 (10th Cir. 2000); *United States v. Davis*, 132 F.3d 1092, 1094 (5th Cir. 1998); *United States v. Kats*, 871 F.2d 105, 108 (9th Cir. 1989) (per curiam); and *United States v. Bay State Ambulance & Hosp. Rental Serv., Inc.*, 874 F.2d 20, 33 (1st Cir. 1989) ("[t]he key to a Medicare Fraud case is the reason for the payment—was the purpose of the payments primarily for inducement."); Accordingly, the AKS prohibits suppliers, including medical device manufacturers such as Abbott, from providing remuneration to healthcare providers in the form of patient referrals when a purpose of the remuneration is to influence the providers' use of its product, which results in reimbursement for the product by a Government Healthcare Program.

55. The AKS further provides that any Medicare claim "that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C. §1320a-7b(g). Under this provision, claims submitted to Government Healthcare Programs that result from violations of the AKS are *per se* false or fraudulent within the meaning of 31 U.S.C. § 3729(a). Accordingly, a violation of the AKS is a *per se* violation of the FCA. *See* the PPACA, Public Law No. 111-148, § 6402(g), which amended the AKS, 42 U.S.C. § 1320a-7b(b), to specifically allow violations of its "anti-kickback" provisions to be enforced under the FCA.

56. The AKS also provides that: "[w]ith respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section." 42 U.S.C. §1320a-7b(h). The PPACA amended the SSA's "intent requirement" to make clear that violations of its anti-kickback provisions, like violations of the FCA, may occur even if an individual "does not have actual knowledge" or "specific intent to commit a violation." Public Law No. 111-148, § 6402(h). In addition, "[T]he focus of the AKS is not the success of the bribe, but the bribe itself."

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United States v. TEVA Pharms. USA, Inc., No. 13 CIV. 3702 (CM), 2016 WL 750720, at *17 (S.D.N.Y. Feb. 22, 2016).

57. As detailed herein, Abbott devised and conducted illicit schemes whereby it paid kickbacks in the form of cash, and cash equivalents, including patient referrals, lavish meals, free marketing and patient practice-building support to healthcare providers, including physicians and hospitals, with the specific intent of inducing these healthcare providers to perform the TMVR procedure using Abbott's MC Device on their cardiac patients covered by Government Healthcare Programs. By knowingly providing these kickbacks to healthcare providers through its illicit schemes, Abbott has caused the submission of thousands of false claims to Medicare, Medicaid, TRICARE, the Veterans Administration healthcare program, and other state and federally funded healthcare programs in violation of the AKS, the FCA, and analogous state laws.

B. STATE LAW

1. California False Claims Act, Cal. Gov't. Code § 12650, *et seq.*

58. Cal. Gov't Code § 12651(a) provides liability for any person who:

> 1) Knowingly presents, or causes to be presented a false or fraudulent claim for payment or approval;
> 2) Knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim;
>
> 3) Conspires to commit a violation of this subdivision;
>
> 4) Has possession, custody, or control of public property or money used or to be used by the state or by any political subdivision and knowingly delivers or causes to be delivered less than all of that property;
>
> 5) Is authorized to make or deliver a document certifying receipt of property used or to be used by the state or by any political subdivision and knowingly makes or delivers a receipt that falsely represents the property used or to be used;
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> 6) Knowingly buys, or receives as a pledge of an obligation or debt, public property from any person who lawfully may not sell or pledge the property;

> 7) Knowingly makes, uses, or causes to be made or used a false record or statement material to an obligation to pay or transmit money or property to the state or to any political subdivision, or knowingly conceals or knowingly and improperly avoids, or decreases an obligation to pay or transmit money or property to the state or to any political subdivision; or
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> 8) Is a beneficiary of an inadvertent submission of a false claim, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the state or the political subdivision within a reasonable time after discovery of the false claim.
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> ... shall be liable to the state or to the political subdivision for three times the amount of damages that the state or political subdivision sustains because of the act of that person. A person who commits any of the following enumerated acts shall also be liable to the state or to the political subdivision for the costs of a civil action brought to recover any of those penalties or damages, and shall be liable to the state or political subdivision for a civil penalty of not less than five thousand five hundred dollars ($5,500) and not more than eleven thousand dollars ($11,000) for each violation, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990, Public Law 101–410 Section 5, 104 Stat. 891, note following 28 U.S.C. Section 2461.

Cal. Gov't Code § 12651 (a).

59. For purposes of the California FCA, the terms "knowing," "knowingly," "claim," and "material" are defined consistent with the definitions provided in the federal FCA. Cal. Gov't Code § 12650(b)(3), (b)(1) and (b)(4).

60. In addition, the payment or receipt of bribes or kickbacks is prohibited under Cal. Bus. & Prof. Code § 650 and 650.1 and is also specifically prohibited in treatment of Medi-Cal patients pursuant to Cal. Welf. & Inst. Code §14107.2.

2. Colorado Medicaid False Claims Act, C.R.S.A. § 25.5-4-304, *et seq.*

61. Colorado's Medicaid False Claims Act, C.R.S.A. § 25.5-4-304, provides for liability for any person who:

> (a) Knowingly presents, or causes to be presented, to an officer or employee of the state a false or fraudulent claim for payment or approval;
>
> (b) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

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> (c) Has possession, custody, or control of property or money used, or to be used, by the state in connection with the "Colorado Medical Assistance Act" and knowingly delivers, or causes to be delivered, less than all of the money or property;
>
> (d) Authorizes the making or delivery of a document certifying receipt of property used, or to be used, by the state in connection with the "Colorado Medical Assistance Act" and, intending to defraud the state, makes or delivers the receipt without completely knowing that the information on the receipt is true;
>
> (e) Knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the state in connection with the "Colorado Medical Assistance Act" who lawfully may not sell or pledge the property;
>
> (f) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state in connection with the "Colorado Medical Assistance Act," or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state in connection with the "Colorado Medical Assistance Act"; ... or
>
> (g) Conspires to commit a violation of paragraphs (a) to (f) of this subsection (1)
>
> …is liable to the state for a civil penalty of not less than five thousand five hundred dollars and not more than eleven thousand dollars; except that these upper and lower limits on liability shall automatically increase to equal the civil penalty allowed under the federal "False Claims Act", 31 U.S.C. sec. 3729, et seq., if and as the penalties in such federal act may be adjusted for inflation as described in said act in accordance with the federal "Civil Penalties Inflation Adjustment Act of 1990", Pub. L. No. 101-410, plus three times the amount of damages that the state sustains because of the act of that person[.]

C.R.S.A. § 25.5-4-305.

62. For purposes of the Colorado Medicaid FCA, the terms "knowing," "knowingly," and "material" are defined consistent with the definitions provided in the federal FCA. C.R.S.A. § 25.5-4-304(3) and (4). The Colorado Medicaid FCA defines the term "claim" in pertinent part, 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, under the "Colorado Medical Assistance Act" that is: (I) Presented to an officer, employee, or agent of the state; or (II) Made

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> 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[.]

Id. at C.R.S.A. § 25.5-4-304(1).

63. In addition, C.R.S.A. § 24-31-809 prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for furnishing any item or service for which payment may be made, in whole or in part, under the Colorado Medicaid program.

3. Connecticut False Claims Act, Conn. Gen. Stat. § 4-274, *et seq.*

64. Conn. Gen. Stat. § 4-275 imposes liability as follows:

> (a) No person shall:
>
> (1) Knowingly present, or cause to be presented, a false or fraudulent claim for payment or approval under a state-administered health or human services program;
>
> (2) Knowingly make, use or cause to be made or used, a false record or statement material to a false or fraudulent claim under a state-administered health or human services program;
>
> (3) Conspire to commit a violation of this section;
>
> (4) Having possession, custody or control of property or money used, or to be used, by the state relative to a state-administered health or human services program, knowingly deliver or cause to be delivered, less property than the amount for which the person receives a certificate or receipt;
>
> (5) Being authorized to make or deliver a document certifying receipt of property used or to be used, by the state relative to a state-administered health or human services program and intending to defraud the state, make or deliver such document without completely knowing that the information on the document is true;
>
> (6) Knowingly buy, or receive as a pledge of an obligation or debt, public property from an officer or employee of the state relative to a state-administered health or human services program, who lawfully may not sell or pledge the property; or

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> (7) Knowingly make, use or cause to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state under a state-administered health or human services program
>
> … [such person] shall be liable to the state for: (1) A civil penalty of not less than five thousand five hundred dollars or more than eleven thousand dollars, or as adjusted from time to time by the federal Civil Penalties Inflation Adjustment Act of 1990, 28 USC 2461, (2) three times the amount of damages that the state sustains because of the act of that person, and (3) the costs of investigation and prosecution of such violation. Liability under this section shall be joint and several for any violation of this section committed by two or more persons.

Conn. Gen. Stat. § 4-275.

65. For purposes of the Connecticut FCA, the terms "knowing," "knowingly," "claim," and "material" are defined consistent with the definitions provided in the federal FCA. Conn. Gen. Stat. § 4-275(1),(2), and (6).

66. In addition, Conn. Gen. Stat. § 53a-161c prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for furnishing any item or service for which payment may be made, in whole or in part, under the Connecticut Medicaid program.

4. Delaware False Claims and Reporting Act, Title 6, Chapter 12, Delaware Code

67. 6 Del. C. § 1201(a) provides liability for any person who:

> (1) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (2) Knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim;
>
> (3)Conspires to commit a violation of defraud the Government by getting a false or fraudulent claim allowed or paid;
>
> (4) Has possession, custody or control of property or money used or to be used by the Government and knowingly delivers or causes to be delivered, less than all of that money or property;

> (5) Is authorized to make or deliver a document certifying receipt of property used or to be used by the Government and, intending to defraud the Government, makes or delivers the receipt without completely knowing that the information on the receipt is true;
>
> (6) Knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Government who may not lawfully sell or pledge the property; or
>
> (7) Knowingly makes, uses, or causes to be made or used a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government
>
> …shall be liable to the Government for a civil penalty of not less than $10,957 and not more than $21,916, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 2015 (28 U.S.C. § 2461, note), for each act constituting a violation of this section, plus 3 times the amount of damages which the Government sustains because of the act of that person.

6 Del. C. § 1201(a).

68. For purposes of the Delaware False Claims and Reporting Act, the terms "knowing," "knowingly," and "material" are defined consistent with the federal FCA. 6 Del. C. § 1202(3) and (4). In pertinent part, the Delaware False Claims and Reporting Act defines "claim" as

> any request or demand, whether under a contract or otherwise, for money or property and whether or not the Government has title to the money or property, that: a. Is presented to an officer, employee, or agent of the Government; or b. Is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the Government: 1. Provides or has provided any portion of the money or property requested or demanded; or 2. Will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded.

Id. at FCA. 6 Del. C. § 1202(1).

69. In addition, 31 Del. C. § 1005 prohibits the solicitation or receipt of any remuneration (including kickbacks, bribes or rebates), directly or indirectly, overtly or covertly, in cash or in kind, in return for the furnishing of any medical care or services for which payment may be made, in whole or in part, under any public assistance program.

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5. Florida False Claims Act, Fla. Stat. § 68.081, *et seq.*

70. Fla. Stat. § 68.083(2) provides liability for any person who:

> (a) Knowingly presents, or causes to be presented a false or fraudulent claim for payment or approval;
>
> (b) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> (c) Conspires to commit a violation of this subsection;
>
> (d) Has possession, custody, or control of property or money used or to be used by the state and knowingly delivers or causes to be delivered less than all of that money or property;
>
> (e) Is authorized to make or deliver a document certifying receipt of property used or to be used by the state and, intending to defraud the state, makes or delivers the receipt without knowing that the information on the receipt is true;
>
> (f) Knowingly buys or receives, as a pledge of an obligation or a debt, public property from an officer or employee of the state who may not sell or pledge the property; or
>
> (g) Knowingly makes, uses, or causes to be made or used a false record or statement material to an obligation to pay or transmit money or property to the state, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state
>
> … [such person] is liable to the state for a civil penalty of not less than $5,500 and not more than $11,000 and for treble the amount of damages the state sustains because of the act of that person.

Fla. Stat. § 68.083(2).

71. In addition, Fla. Stat. § 409.920(2)(a) makes it a crime to:

> (3) Knowingly charge, solicit, accept, or receive anything of value, other than an authorized copayment from a Medicaid recipient, from any source in addition to the amount legally payable for an item or service provided to a Medicaid recipient under the Medicaid program or knowingly fail to credit the agency or its fiscal agent for any payment received from a third-party source; or

* * *

> (5) Knowingly, solicit, offer, pay or receive any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for referring an individual to a person for the furnishing of any item or service for which payment may be made, in whole or in part, under the Medicaid program, or in return for obtaining, purchasing, leasing, ordering, or arranging, for or recommending, obtaining, purchasing, leasing, or ordering any goods, facility, item, or service, for which payment may be made, in whole or in part, under the Medicaid program.

72. For purposes of the Florida FCA, the terms "knowing," "knowingly," "material," and "claim" are defined consistent with the federal FCA. Fla. Stat. § 68.082(1)(a),(c) and (d).

73. Fla. Stat. §456.054(2) also prohibits the offering, payment, solicitation, or receipt of a kickback to a healthcare provider, whether directly or indirectly, overtly or covertly, in cash or in kind, in exchange for referring or soliciting patients.

6. Georgia False Medicaid Claims Act, Ga. Code Ann., § 49-4-168, *et seq*

74. The Georgia False Medicaid Claims Act imposes liability on any person who:

> (1) Knowingly presents, or causes to be presented to the Georgia Medicaid program a false or fraudulent claim for payment or approval;
>
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> (3) Conspires to commit a violation of paragraph (1), (2), (4), (5), (6), or (7) of this subsection;
>
> (4) Has possession, custody, or control of property or money used or to be used by the Georgia Medicaid program and, knowingly delivers, or causes to be delivered, less than all of such money or property;
>
> (5) Is authorized to make or deliver a document certifying receipt of property used, or to be used, by the Georgia Medicaid program and, intending to defraud the Georgia Medicaid program, makes or delivers the receipt without completely knowing that the information on the receipt is true;
>
> (6) Knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Georgia Medicaid program who lawfully may not sell or pledge the property; or

> (7) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit property or money to the Georgia Medicaid program, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit property or money to the Georgia Medicaid program
>
> … shall be liable to the State of Georgia for a civil penalty consistent with the civil penalties provision of the federal False Claims Act, 31 U.S.C. 3729(a), as adjusted by the federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461; Public Law 101-410), and as further amended by the federal Civil Penalties Inflation Adjustment Improvements Act of 2015 (Sec. 701 of Public Law 114-74), plus three times the amount of damages which the Georgia Medicaid program sustains because of the act of such person.

Ga. Code Ann., § 49-4-168.1.

75. For purposes of the Georgia False Medicaid Claims Act, the terms "knowing," "knowingly," and "material" are defined consistent with the federal FCA. Ga. Code Ann., § 49-4-168(2) and (3). In pertinent part, the Georgia False Medicaid Claims Act defines "claim" as

> any request or demand, whether under a contract or otherwise, for money or property, whether or not the Georgia Medicaid program or this state has title to such money or property, which is made to the Georgia Medicaid program, to any officer, employee, fiscal intermediary, grantee, agent, or contractor of the Georgia Medicaid program, or to other persons or entities if it results in payments by the Georgia Medicaid program, if the Georgia Medicaid program provides, has provided, or will provide any portion of the money or property requested or demanded; if the Georgia Medicaid program will reimburse the contractor, grantee, or other recipient for any portion of the money or property requested or demanded; or if the money or property is to be spent or used on behalf of or to advance the Georgia Medicaid program. A claim includes a request or demand made orally, in writing, electronically, or magnetically. Each claim may be treated as a separate claim[.]

Id. at Ga. Code Ann., § 49-4-168(1).

7. Hawaii False Claims Act, Haw. Rev. Stat. § 661-21, *et seq*.

76. Haw. Rev. Stat. § 661-21(a) provides liability for any person who:

> (1) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (2) Knowingly makes, uses, or causes to be made or used, a statement material to a false or fraudulent claim;

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(7) Is a beneficiary of an inadvertent submission of a false claim to the State, who subsequently discovers the falsity of the claim, and fails to disclose the false claim to the State within a reasonable time after discovery of the false claim; or

(8) Conspires to commit any of the conduct described in this subsection

… [such person] shall be liable to the State for a civil penalty of not less than $11,463 and not more than $22,927, plus three times the amount of damages that the State sustains due to the act of that person; provided that for 2020 and annually thereafter, the minimum and maximum penalty amounts shall be the same as the minimum and maximum civil monetary penalty amounts authorized for the federal False Claims Act, title 31 United States Code section 3729, adjusted for cost-of-living adjustments and for the same effective dates, as adopted by the United States Department of Justice by federal rule in title 28 Code of Federal Regulations part 85, pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, P.L. 101-410, title 31 United States Code section 3717.

Haw. Rev. Stat. § 661-21(a).

77. For purposes of the Hawaii FCA, the terms "knowing," "knowingly," "claim," and "material" are defined consistent with the federal FCA. Haw. Rev. Stat. § 661-21(e).

8. Illinois False Claims Act, 740 ILCS 175, *et seq*.

78. 740 ILCS 175/3(a) provides liability for any person who:

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

(B) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

(C) Conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G) defraud the State by getting a false or fraudulent claim allowed or paid;

(D) Has possession, custody, or control of property or money used, or to be used, by the State and knowingly delivers, or causes to be delivered, less than all the money or property;

(E) Is authorized to make or deliver a document certifying receipt of property used, or to be used, by the State and, intending to defraud the

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> State, makes or delivers the receipt without completely knowing that the information on the receipt is true;
>
> (F) Knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the State, or a member of the Guard, who lawfully may not sell or pledge property; or
>
> (G) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the State, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the State
>
> … is liable to the State for a civil penalty of not less than the minimum amount and not more than the maximum amount allowed for a civil penalty for a violation of the federal False Claims Act (31 U.S.C. 3729 et seq.) as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461), plus 3 times the amount of damages which the State sustains because of the act of that person.

740 ILCS 175/3(a).

79. For purposes of the Illinois FCA, the terms "knowing," "knowingly," "claim," and "material" are defined consistent with the federal FCA. 740 ILCS 175(b)(1) and (4) and 740 ILCS 175(b)(2).

80. In addition, 305 ILCS 5/8A-3(b) of the Illinois Public Aid Code (Vendor Fraud and Kickbacks) prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for furnishing any item or service for which payment may be made, in whole or in part, under the Illinois Medicaid program.

9. Indiana False Claims and Whistleblower Protection Act, Indiana Code 5-11-5.5, *et seq.*

81. The Indiana False Claims and Whistleblower Protection Act, Indiana Code 5-11-5.5, *et seq*. imposes liability on:

> (b) A person who knowingly or intentionally:
>
> (1) Presents a false claim to the state for payment or approval;

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> (2) Makes or uses a false record or statement to obtain payment or approval of a false claim from the state;
>
> (3) With intent to defraud the state, delivers less money or property to the state than the amount recorded on the certificate or receipt the person receives from the state;
>
> (4) With intent to defraud the state, authorizes issuance of a receipt without knowing that the information on the receipt is true;
>
> (5) Receives public property as a pledge of an obligation on a debt from an employee who is not lawfully authorized to sell or pledge the property;
>
> (6) Makes or uses a false record or statement to avoid an obligation to pay or transmit property to the state;
>
> (7) Conspires with another person to perform an act described in subdivisions (1) through (6); or
>
> (8) Causes or induces another person to perform an act described in subdivisions (1) through (6). . . .
>
> …[such person is] liable to the state for a civil penalty of at least five thousand dollars ($5,000) and for up to three (3) times the amount of damages sustained by the state. In addition, a person who violates this section is liable to the state for the costs of a civil action brought to recover a penalty or damages.

Indiana Code 5-11-5.5-2.

82. For purposes of the Indiana False Claims and Whistleblower Protection Act, the terms "knowing" and "knowingly" are defined consistent with the federal FCA. Indiana Code 5-11-5.5-1(4). In pertinent part, the Indiana False Claims and Whistleblower Protection Act defines "claim" as

> a request or demand for money or property that is made to a contractor, grantee, or other recipient if the state: (A) provides any part of the money or property that is requested or demanded; or (B) will reimburse the contractor, grantee, or other recipient for any part of the money or property that is requested or demanded[.]

Id. at Indiana Code 5-11-5.5-1(1).

83. In addition, Indiana Code § 5-11-5.5, *et seq.,* prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or

indirectly, overtly or covertly, in cash or in kind, in return for furnishing any item or service for which payment may be made, in whole or in part, under the Indiana Medicaid program.

10. Iowa False Claims Act, I.C.A. § 685.1, *et seq.*

84. Iowa False Claims Act, I.C.A. § 685.2, in pertinent part, provides for liability for any person who:

> (a) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (b) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; and/or
>
> (c) Conspires to commit a violation of paragraph "a," "b," "d," "e," "f," or "g"
>
> … is liable to the state for a civil penalty of not less than and not more than the civil penalty allowed under the federal False Claims Act, as codified in 31 U.S.C. § 3729 et seq., as may be adjusted in accordance with the inflation adjustment procedures prescribed in the federal Civil Penalties Inflation Adjustment Act of 1990, Pub. L. No. 101-410, for each false or fraudulent claim, plus three times the amount of damages which the state sustains.

I.C.A. § 685.2.

85. For purposes of the Iowa FCA, the terms "knowing," "knowingly," "claim," and "material" are defined consistent with the federal FCA. I.C.A. § 685.1(1),(7), and (8).

11. Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 46:437.1, *et seq.*

86. La. Rev. Stat. Ann. § 46:438.3 provides:

> (A) No person shall knowingly present or cause to be presented, a false or fraudulent claim;
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> (B) No person shall knowingly engage in misrepresentation or make, use, or cause to be made or used, a false record or statement material to a false or fraudulent claim;

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> (C) No person shall knowingly make, use, or cause to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the medical assistance programs, or to knowingly conceal, avoid, or decrease an obligation to pay or transmit money or property to the medical assistance programs; and
>
> (D) No person shall conspire to defraud, or attempt to defraud, the medical assistance programs through misrepresentation or by obtaining, or attempting to obtain, payment for a false or fraudulent claim
>
> … (2) Except as limited by this Section, any person who is found to have violated R.S. 46:438.3 shall be subject to a civil fine in an amount not to exceed three times the amount of actual damages sustained by the medical assistance programs as a result of the violation.
>
> C. Civil monetary penalty. (1) In addition to the actual damages provided in Subsection A of this Section and the civil fine imposed pursuant to Subsection B of this Section, the following civil monetary penalties shall be imposed on the violator:
>
> (a) Not less than five thousand five hundred dollars but not more than eleven thousand dollars for each false or fraudulent claim, misrepresentation, illegal remuneration, or other prohibited act as contained in R.S. 46:438.2, 438.3, or 438.4.

La. Rev. Stat. Ann. § 46:438.3 and § 46:438.6.

87. For purposes of the Louisiana Medical Assistance Programs Integrity Law the terms "knowing," "knowingly," "claim," and "material" are defined consistent with the federal FCA. La. Rev. Stat. Ann. § 46:437.3(50, (11), and (13).

88. In addition, La. Rev. Stat. Ann. § 438.2(A) prohibits the solicitation, receipt, offering or payment of any financial inducements, including kickbacks, bribes and/or rebates, directly or indirectly, overtly or covertly, in cash or in kind, for furnishing healthcare goods or services paid for, in whole or in part, by the Louisiana medical assistance programs.

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2 **12. Michigan Medicaid False Claims Act, Mich. Comp. Laws Ann. § 400.603, *et seq.***
3 89. Michigan's Medicaid False Claims Act, Mich. Comp. Laws Ann. §
4 400.603, *et seq*. provides, in pertinent part, as follows:
5
6 Sec. 3. (1) A person shall not knowingly make or cause to be made a
7 false statement or false representation of a material fact in an application for Medicaid benefits; and
8 (2) A person shall not knowingly make or cause to be made a
9 false statement or false representation of a material fact for use in determining rights to a Medicaid benefit....
10 … A person who receives a benefit that the person is not entitled to
11 receive by reason of fraud or making a fraudulent statement or knowingly concealing a material fact, or who engages in any conduct
12 prohibited by this statute, shall forfeit and pay to the state the full amount received, and for each claim a civil penalty of not less than $
13 5,000.00 or more than $ 10,000.00 plus triple the amount of damages suffered by the state as a result of the conduct by the person.
14 Mich. Comp. Laws Ann. § 400.603 and § 400.612.
15 90. For purposes of the Michigan Medicaid False Claims Act FCA the terms
16 "knowing" and "knowingly" are defined as
17
18 a person is in possession of facts under which he or she is aware or should be aware of the nature of his or her conduct and that his or her
19 conduct is substantially certain to cause the payment of a medicaid benefit. Knowing or knowingly includes acting in deliberate
20 ignorance of the truth or falsity of facts or acting in reckless disregard of the truth or falsity of facts. Proof of specific intent to defraud is not
21 required.
22 Mich. Comp. Laws Ann. § 400.602(f).
23 91. For purposes of the Michigan Medicaid False Claims Act FCA the term
24 "claim" is defined as
25 any attempt to cause the department of community health to pay out sums of
26 money under the social welfare act.
27

Id. at Mich. Comp. Laws Ann. § 400.602(b).

92. In addition, Mich. Comp. Laws Ann. § 400.604 prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for furnishing any item or service for which payment may be made, in whole or in part, under the Michigan Medicaid program.

13. Minnesota False Claims Act, M.S.A. § 15C.01, *et seq.*

93. Minnesota False Claims Act, M.S.A. § 15C.02, provides for liability for any person who:

> (1) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (2) Knowingly makes or uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> (3) Knowingly conspires to commit a violation of clause (1), (2), (4), (5), (6), or (7);
>
> (4) Has possession, custody, or control of property or money used, or to be used, by the state or a political subdivision and knowingly delivers or causes to be delivered less than all of that money or property;
>
> (5) Is authorized to make or deliver a receipt for money or property used, or to be used, by the state or a political subdivision, and intending to defraud the state or a political subdivision, makes or delivers the receipt without completely knowing that the information on the receipt is true;
>
> (6) Knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the state or a political subdivision who lawfully may not sell or pledge the property; and/or
>
> (7) Knowingly makes or uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state or a political subdivision, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state or a political subdivision.
>
> … A person who commits any act described in clauses (1) to (7) is

> liable to the state or the political subdivision for a civil penalty in the amounts set forth in the federal False Claims Act, United States Code, title 31, section 3729, and as modified by the federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, plus three times the amount of damages that the state or the political subdivision sustains because of the act of that person.

M.S.A. § 15C.02.

94. For purposes of the Minnesota FCA the terms "knowing," "knowingly," "claim," and "material" are defined consistent with the federal FCA. M.S.A. § 15C.01(2), (3), and (4).

95. In addition, M.S.A. § 256B.0914, prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for furnishing any item or service for which payment may be made, in whole or in part, under the Minnesota Medicaid program.

14. Montana False Claims Act, MCA § 17-8-401, *et seq.*

96. Montana's False Claims Act, MCA § 17-8-403, provides for liability for any person who:

> (a) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (b) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> (c) Conspires to commit a violation of this subsection (1);
>
> (d) Has possession, custody, or control of public property or money used or to be used by the governmental entity and knowingly delivers or causes to be delivered less than all of the property or money;
>
> (e) Is authorized to make or deliver a document certifying receipt of property used or to be used by the governmental entity and, with the intent to defraud the governmental entity or to willfully conceal the property, makes or delivers a receipt without completely knowing that the information on the receipt is true;
>
> (f) Knowingly buys or receives as a pledge of an obligation or debt public property of the governmental entity from any person who may not lawfully sell or pledge the property;

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> (g) Knowingly makes, uses, or causes to be made or used a false record or statement material to an obligation to pay or transmit money or property to the governmental entity or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to a governmental entity; or
>
> (h) as a beneficiary of an inadvertent submission of a false or fraudulent claim to the governmental entity, subsequently discovers the falsity of the claim or that the claim is fraudulent and fails to disclose the false or fraudulent claim to the governmental entity within a reasonable time after discovery of the false or fraudulent claim
>
> … In a civil action brought under 17-8-405 or 17-8-406, a court shall assess a civil penalty of not less than $5,500 and not more than $11,000 for each act specified in this section, plus not less than two times and not more than three times the amount of damages that a governmental entity sustains…

MCA § 17-8-403.

97. For purposes of the Montana FCA the terms "knowing," "knowingly," "claim," and "material" are defined consistent with the federal FCA. MCA § 17-8-402(1), (4), and (5).

98. In addition, MCA § 45-6-313 prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for furnishing any item or service for which payment may be made, in whole or in part, under the Montana Medicaid program.

15. Nevada False Claims Act, N.R.S. § 357.010, *et seq.*

99. N.R.S. § 357.040(1) provides liability for any person who:

> (a) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (b) Knowingly makes or uses, or causes to be made or used, a false record or statement that is material to a false or fraudulent claim;
>
> (c) Has possession, custody or control of public property or money used or to be used by the State or a political subdivision and knowingly delivers or causes to be delivered to the State or a political subdivision less money or property than the amount of which the person has possession, custody or control;

> (d) Is authorized to prepare or deliver a document that certifies receipt of money or property used or to be used by the State or a political subdivision and knowingly prepares or delivers such a document without knowing that the information on the document is true.
>
> * * *
>
> (h) Is a beneficiary of an inadvertent submission of a false claim and, after discovering the falsity of the claim, fails to disclose the falsity to the state or political subdivision within a reasonable time; and/or
>
> (i) Conspires to commit any of the acts set forth in this subsection.
>
> ... is liable for: (a) Three times the amount of damages sustained by the State or political subdivision, whichever is affected, because of the act of the person; (b) The costs of a civil action brought to recover the damages described in paragraph (a); and (c) Except as otherwise provided in this paragraph, a civil penalty of not less than $5,500 or more than $11,000. A civil penalty imposed pursuant to this paragraph must correspond to any adjustments in the monetary amount of a civil penalty for a violation of the federal False Claims Act, 31 U.S.C. § 3729(a), made by the Attorney General of the United States in accordance with the Federal Civil Penalties Inflation Adjustment Act of 1990, Pub. L. 101-410, as amended.

N.R.S. § 357.040.

100. For purposes of the Nevada FCA the terms "knowing," "knowingly," "claim," and "material" are defined consistent with the federal FCA. N.R.S. § 357.040(3), § 357.022, and § 357.020.

101. In addition, N.R.S. § 422.560 prohibits the solicitation, acceptance or receipt of anything of value in connection with the provision of medical goods or services for which payment may be made, in whole or in part, under the Nevada Medicaid program.

16. New Jersey False Claims Act, N.J.S.A. § 2A:32C-1, *et seq.*

102. The New Jersey False Claims Act, N.J.S.A. § 2A:32C-3, provides for liability for any person who:

> a. Knowingly presents, or causes to be presented, to an employee, officer or agent of the State, or to any contractor, grantee, or other recipient of State funds, a false or fraudulent claim for payment or approval;

b. Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;

c. Conspires to defraud the State by getting a false or fraudulent claim allowed or paid by the State;

d. Has possession, custody, or control of public property or money used or to be used by the State and knowingly delivers, or causes to be delivered, less property than the amount for which the person receives a certificate or receipt;

e. Is authorized to make or deliver a document certifying receipt of property used or to be used by the State and, intending to defraud the entity, makes or delivers a receipt without completely knowing that the information on the receipt is true;

f. Knowingly buys, or receives as a pledge of an obligation or debt, public property from any person who lawfully may not sell or pledge the property; or

g. 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.
… A person shall be jointly and severally liable to the State for a civil penalty of not less than and not more than the civil penalty allowed under the federal False Claims Act (31 U.S.C.s.3729 et seq.), as may be adjusted in accordance with the inflation adjustment procedures prescribed in the Federal Civil Penalties Inflation Adjustment Act of 1990, Pub.L.101-410, for each false or fraudulent claim, plus three times the amount of damages which the State sustains, if the person commits any of the following acts.

N.J.S.A. § 2A:32C-3.

103. For purposes of the New Jersey FCA the terms "knowing," "knowingly," and "claim" are defined consistent with the federal FCA. N.J.S.A. § 2A:32C-2.

104. In addition, N.J.S.A. § 30:4D-17 prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for furnishing any item or service for which payment may be made, in whole or in part, under the New Jersey Medicaid program.

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17. New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §§ 27-14-1, *et seq.*

105. New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §§ 27-14-1, *et seq.* states that a person commits an unlawful act if the person:

> (1) Presents, or causes to be presented, to the state a claim for payment under the medicaid program knowing that such claim is false or fraudulent;
>
> (2) Presents, or causes to be presented, to the state a claim for payment under the medicaid program knowing that the person receiving a medicaid benefit or payment is not authorized or is not eligible for a benefit under the medicaid program;
>
> (3) Makes, uses or causes to be made or used a record or statement to obtain a false or fraudulent claim under the medicaid program paid for or approved by the state knowing such record or statement is false;
>
> (4) Conspires to defraud the state by getting a claim allowed or paid under the medicaid program knowing that such claim is false or fraudulent; or
>
> (5) Makes, uses or causes to be made or used a record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the state, relative to the medicaid program, knowing that such record or statement is false.
>
> …A person [who] commits an unlawful act and shall be liable to the state for three times the amount of damages that the state sustains as a result of the act…

N.M. Stat. Ann. §27-14-4.

106. In pertinent part, the New Mexico Medicaid FCA defines "claim" as

> a written or electronically submitted request for payment of health care services pursuant to the medicaid program;

Id. at , N.M. Stat. Ann. §§ 27-14-3(a).

107. In addition, the New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. § 44-9-2 *et seq.*, which provides, in pertinent part, as follows:

> A person shall not:
>
> (1) Knowingly present, or cause to be presented, to an employee, officer or agent of the state or a political subdivision or to a contractor, grantee

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> or other recipient of state or political subdivision funds a false or fraudulent claim for payment or approval;
>
> (2) Knowingly make or use, or cause to be made or used, a false, misleading or fraudulent record or statement to obtain or support the approval of or the payment on a false or fraudulent claim;
>
> (3) Conspire to defraud the state or a political subdivision by obtaining approval or payment on a false or fraudulent claim;
>
> (4) Conspire to make, use or cause to be made or used, a false, misleading or fraudulent record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the state or a political subdivision;
>
> (5) When in possession, custody or control of property or money used or to be used by the state or a political subdivision, knowingly deliver or cause to be delivered less property or money than the amount indicated on a certificate or receipt;
>
> (6) When authorized to make or deliver a document certifying receipt of property used or to be used by the state or a political subdivision, knowingly make or deliver a receipt that falsely represents a material characteristic of the property;
>
> (7) Knowingly buy, or receive as a pledge of an obligation or debt, public property from any person that may not lawfully sell or pledge the property;
>
> (8) Knowingly make or use, or cause to be made or used, a false, misleading or fraudulent record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the state or a political subdivision; or
>
> (9) As a beneficiary of an inadvertent submission of a false claim and having subsequently discovered the falsity of the claim, fail to disclose the false claim to the state or political subdivision within a reasonable time after discovery
>
> … [such person] shall be liable for: (1) three times the amount of damages sustained by the state or political subdivision because of the violation; (2) a civil penalty of not less than five thousand dollars ($5,000) and not more than ten thousand dollars ($10,000) for each violation.

N.M. Stat. Ann. § 44-9-3.

108. For purposes of the New Mexico Fraud Against Taxpayers Act the terms "knowing" and "knowingly" are defined consistent with the federal FCA. N.M. Stat. Ann. § 44-9-2(C).

109. In addition, N.M. Stat. Ann. §§ 30-44-7, *et seq.*, prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for furnishing any item or service for which payment may be made, in whole or in part, under the New Mexico Medicaid program.

18. New York False Claims Act, State Finance Law § 189

110. The New York State False Claims Act, State Finance Law § 189 imposes liability on any person who:

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

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

(c) Conspires to commit a violation of paragraph (a), (b), (d), (e), (f) or (g) of this subdivision;.

(d) Has possession, custody, or control of property or money used, or to be used, by the state or a local government and knowingly delivers, or causes to be delivered, less than all of that money or property;

(e) Is authorized to make or deliver a document certifying receipt of property used, or to be used, by the state or a local government and, intending to defraud the state or a local government, makes or delivers the receipt without completely knowing that the information on the receipt is true;

(f) Knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the state or a local government knowing that the officer or employee violates a provision of law when selling or pledging such property; or

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> (g) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state or a local government
>
> … shall be liable to the state or a local government, as applicable, for a civil penalty of not less than six thousand dollars and not more than twelve thousand dollars, as adjusted to be equal to the civil penalty allowed under the federal False Claims Act, 31 U.S.C. sec. 3729, et seq., as amended, as adjusted for inflation by the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended (28 U.S.C. 2461 note; Pub. L. No. 101-410), plus three times the amount of all damages, including consequential damages, which the state or local government sustains because of the act of that person.

New York State False Claims Act, State Finance Law § 189.

111. For purposes of the New York State FCA the terms "knowing," "knowingly," "claim," and "material" are defined consistent with the federal FCA. State Finance Law § 188910, (3), and (5).

112. In addition, New York law prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for furnishing any item or service for which payment may be made, in whole or in part, under the New York Medicaid program.

19. North Carolina False Claims Act, N.C.G.S.A. § 1-605, *et seq*.

113. North Carolina's False Claims Act, N.C.G.S.A. § 1-607, provides for liability for any person who:

> (1) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> (3) Conspires to commit a violation of subdivision (1), (2), (4), (5), (6), or (7) of this section;
>
> (4) Has possession, custody, or control of property or money used or to be used by the State and knowingly delivers or causes to be delivered less than all of that money or property;

(5) Is authorized to make or deliver a document certifying receipt of property used or to be used by the State and, intending to defraud the State, makes or delivers the receipt without completely knowing that the information on the receipt is true;

(6) Knowingly buys, or receives as a pledge of an obligation or debt, public property from any officer or employee of the State who lawfully may not sell or pledge the property; or

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

[…]Any person who commits any of the following acts 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 who commits any of the following acts also 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.A. § 1-607.

114. For purposes of the North Carolina FCA the terms "knowing," "knowingly," "claim," and "material" are defined consistent with the federal FCA. N.C.G.S.A. § 1-606(2), (4), and (5).

115. In addition, N.C.G.S.A. § 108A-63 prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for furnishing any item or service for which payment may be made, in whole or in part, under the North Carolina Medicaid program.

20. Oklahoma Medicaid False Claims Act, 63 Ok. St. Ann. § 5053, *et seq.*

116. Oklahoma's Medicaid False Claims Act, 63 Okl. St. Ann. § 5053.1, provides for liability for any person who:

1. Knowingly presents, or causes to be presented,, a false or fraudulent claim

for payment or approval;

2. Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

3. Conspires to commit a violation of the Oklahoma Medicaid False Claims Act;

4. Has possession, custody, or control of property or money used, or to be used, by the state and, knowingly delivers, or causes to be delivered, less than all of such money or property;

5. Is authorized to make or deliver a document certifying receipt of property used, or to be used, by the state and, intending to defraud the State, makes or delivers the receipt without completely knowing that the information on the receipt is true;

6. Knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the state, who lawfully may not sell or pledge the property; or

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

…is liable to the State of Oklahoma for a civil penalty consistent with the civil penalties provision of the Federal False Claims Act, 31 U.S.C. 3729(a), as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 101-410), and as further amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of Public Law 114-74), plus three times the amount of damages which the state sustains because of the act of that person.

63 Okl. St. Ann. § 5053.1.

117. For purposes of the Oklahoma Medicaid FCA the terms "knowing," "knowingly," "claim," and "material" are defined consistent with the federal FCA. 63 Okl. St. Ann. § 5053.1(1), (2), and (3).

118. In addition, 56 Okl. St. Ann. § 1005 prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for furnishing any item or service for which payment may be made in whole or in part, under the Oklahoma Medicaid program.

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21. Rhode Island False Claims Act, Gen. Laws 1956, § 9-1.1-1, *et seq.*

119. Rhode Island's False Claims Act, Gen. Laws 1956, § 9-1.1-3, provides for liability for any person who:

> (1) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> (3) Conspires to commit a violation of subsection (a)(1), (a)(2), (a)(4), (a)(5), (a)(6), or (a)(7);
>
> (4) Has possession, custody, or control of property or money used, or to be used, by the state and, knowingly delivers, or causes to be delivered, less property than all of that money or property;
>
> (5) Is authorized to make or deliver a document certifying receipt of property used, or to be used, by the state and, intending to defraud the state, makes or delivers the receipt without completely knowing that the information on the receipt is true;
>
> (6) Knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the state, or a member of the guard, who lawfully may not sell or pledge the property; or
>
> (7) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state.
>
> …is liable to the state for a civil penalty in an amount equal to the civil penalty set forth in the Federal False Claims Act, following the Federal Civil Penalties Inflation Agreement Act of 1990 (31 U.S.C. § 3729(a)), Pub. L. No. 101-410 section 5, 104 Stat. 891, note following 28 U.S.C. § 2461, as amended and annually adjusted by the Federal Civil Penalties Inflation Adjustment Improvements Act of 2015, plus three (3) times the amount of damages the state sustains because of the act of that person. A person violating this subsection (a) shall also be liable to the state for the costs of a civil action brought to recover any penalty or damages.

Gen. Laws 1956, § 9-1.1-3.

120. For purposes of the Rhode Island FCA the terms "knowing," "knowingly," "claim," and "material" are defined consistent with the federal FCA. Gen. Laws 1956, §

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9-1.1-3(b)(1), (2), and (3).

121. In addition, Gen. Laws 1956, § 40-8.2-9 prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for furnishing any item or service for which payment may be made, in whole or in part, under the Rhode Island Medicaid program.

22. Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181, *et seq.*

122. Section 71-5-182(a)(1) provides liability for any person who:

> (A) Knowingly presents, or causes to be presented a false or fraudulent claim for payment or approval under the medicaid program;
>
> (B) Knowingly makes or uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim under the medicaid program;
>
> (C) Conspires to commit a violation of subdivision (a)(1)(A), (a)(1)(B), or (a)(1)(D); or
>
> (D) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money, or property to the state, or knowingly conceals, or knowingly and improperly, avoids, or decreases an obligation to pay or transmit money or property to the state, relative to the medicaid program
>
> … is liable to the state for a civil penalty of not less than five thousand dollars ($5,000) and not more than twenty-five thousand dollars ($25,000), adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. § 2461 note); Public Law 101-410, plus three (3) times the amount of damages which the state sustains because of the act of that person.

Tenn. Code Ann. § 71-5-182.

123. For purposes of the Tennessee Medicaid FCA the terms "knowing," "knowingly," "claim," and "material" are defined consistent with the federal FCA. Tenn. Code Ann. § 71-5-182(c), (b), and (e).

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23. Texas Medicaid Fraud Prevention Act, V.T.C.A. Hum. Res. Code § 36.001, *et seq.*

124. V.T.C.A. Hum. Res. Code § 36.002 provides liability for any person who:

> (1) Knowingly makes or causes 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;
>
> (2) Knowingly conceals or fails 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;
>
> * * *
>
> (4) Knowingly makes, causes to be made, induces, or seeks to induce the making of a false statement or misrepresentation of material fact concerning:
>
> * * *
>
> (B) Information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program;
>
> (5) Except as authorized under the Medicaid program, knowingly pays, charges, solicits, accepts, or receives, in addition to an amount paid under the Medicaid program, a gift, money, a donation, or other consideration as a condition to the provision of a service or product or the continued provision of a service or product if the cost of the service or product is paid for, in whole or in part, under the Medicaid program;
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> * * *
>
> (9) Conspires to commit a violation of Subdivision (1), (2), (3), (4), (5), (6), (7), (8), (10), (11), (12), or (13);
>
> * * *
>
> (12) Knowingly makes, uses, or causes the making or use of a false record or statement material to an obligation to pay or transmit money or property to this state under the Medicaid program, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to this state under the Medicaid program; or
>
> (13) Knowingly engages in conduct that constitutes a violation under Section 32.039(b)

> …Except as provided by Subsection (c), a person who commits an unlawful act is liable to the state for a civil penalty of not less than $5,500 or the minimum amount imposed as provided by 31 U.S.C. Section 3729(a), if that amount exceeds $5,500, and not more than $11,000 or the maximum amount imposed as provided by 31 U.S.C. Section 3729(a), if that amount exceeds $11,000, for each unlawful act committed by the person that does not result in injury to a person described by Paragraph (A); and (4) two times the amount of the payment or the value of the benefit described by Subdivision (1).

V.T.C.A. Hum. Res. Code § 36.052.

125. For purposes of the Texas Medicaid Fraud Prevention Act the term "knowingly" is defined similar to the federal FCA. V.T.C.A. Hum. Res. Code § 36.0011(1-3b). For purposes of the Texas Medicaid Fraud Prevention Act the term "material" is defined as

> "Material" means having a natural tendency to influence or to be capable of influencing.

V.T.C.A. Hum. Res. Code § 36.001(5-a).

126. In pertinent part, the Texas Medicaid Fraud Prevention Act defines "claim" as

> (1) a written or electronically submitted request or demand that:(A) is signed by a provider or a fiscal agent and that identifies a product or service provided or purported to have been provided to a Medicaid recipient as reimbursable under the Medicaid program, without regard to whether the money that is requested or demanded is paid; or(B) states the income earned or expense incurred by a provider in providing a product or a service and that is used to determine a rate of payment under the Medicaid program.

Id. at V.T.C.A. Hum. Res. Code § 36.001(1).

127. In addition, under V.T.C.A. Hum. Res. Code § 32.039(b), a person commits a violation if that person:

> (1) Presents or causes to be presented to the commission a claim that contains a statement or representation the person knows or should know to be false;

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(1-b) Solicits or receives, directly or indirectly, overtly or covertly any remuneration, including any kickback, bribe, or rebate, in cash or in kind for referring an individual to a person for the furnishing of, or for arranging the furnishing of, any item or service for which payment may be made, in whole or in part, under the medical assistance program, provided that this subdivision does not prohibit the referral of a patient to another practitioner within a multispecialty group or university medical services research and development plan (practice plan) for medically necessary services;

(1-c) Solicits or receives, directly or indirectly, overtly or covertly any remuneration, including any kickback, bribe, or rebate, in cash or in kind for purchasing, leasing, or ordering, or arranging for or recommending the purchasing, leasing, or ordering of, any good, facility, service, or item for which payment may be made, in whole or in part, under the medical assistance program;

(1-d) 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 refer an individual to another person for the furnishing of, or for arranging the furnishing of, any item or service for which payment may be made, in whole or in part, under the medical assistance program, provided that this subdivision does not prohibit the referral of a patient to another practitioner within a multispecialty group or university medical services research and development plan (practice plan) for medically necessary services;

(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; or

(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…

24. Virginia Fraud Against Tax Payers Act, § 8.01-216-3a

128. The Virginia Fraud Against Tax Payers Act, §8.01-216.3a provides liability for any person who:

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> (1) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
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> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> (3) Conspires to commit a violation of subdivision 1, 2, 4, 5, 6, 7, 8, or 9;
>
> (4) Has possession, custody, or control of property or money used, or to be used, by the Commonwealth and knowingly delivers, or causes to be delivered, less than all such money or property;
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> * * *
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> (7) Is authorized to make or deliver a document certifying receipt of property used, or to be used, by the Commonwealth and, intending to defraud the Commonwealth, makes or delivers the receipt without completely knowing that the information on the receipt is true;
>
> (8)Knowingly buys or receives as a pledge of an obligation or debt, public property from an officer or employee of the Commonwealth who lawfully may not sell or pledge the property; or
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> (9)Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Commonwealth or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Commonwealth.
>
> … shall be liable to the Commonwealth for a civil penalty of not less than $10,957 and not more than $21,916, except that these lower and upper limits on liability shall automatically be adjusted to equal the amounts allowed under the Federal False Claims Act, 31 U.S.C. § 3729 et seq., as amended, as such penalties in the Federal False Claims Act are adjusted for inflation by the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended (28 U.S.C. § 2461 Note, P.L. 101-410), plus three times the amount of damages sustained by the Commonwealth.

§8.01-216.3.

129. For purposes of the Virginia Fraud Against Taxpayers Act the terms "knowing," "knowingly," "claim," and "material" are defined consistent with the federal FCA. §8.01-216.2 and §8.01-216.3c.

130. In addition, VA Code Ann. § 32.1-315 prohibits the solicitation, receipt or

offering of any remuneration, including any bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for furnishing any good, service or item for which payment may be made, in whole or in part, under the Virginia Medicaid program.

25. Washington State Medicaid Fraud False Claims Act, RCWA 74.66.005, *et seq.*

131. RCWA 74.66.020, in pertinent part, provides for liability for any person who:

> (a) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
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> (b) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> (c) Conspires to commit one or more of the violations in this subsection (1);
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> (d) Is authorized to make or deliver a document certifying receipt of property used, or to be used, by the government entity and, intending to defraud the government entity, makes or delivers the receipt without completely knowing that the information on the receipt is true;
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> (e) Is authorized to make or deliver a document certifying receipt of property used, or to be used, by the government entity and, intending to defraud the government entity, makes or delivers the receipt without completely knowing that the information on the receipt is true;
>
> (f) Knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the government entity who lawfully may not sell or pledge property; or
>
> (g) Knowingly makes, uses, or causes to be made or used a false record or statement material to an obligation to pay or transmit money or property to the government entity, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the government entity
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> […]Subject to subsections (2) and (4) of this section, a person is liable to the government entity for a civil penalty of not less than the greater of ten thousand nine hundred fifty-seven dollars or the minimum inflation adjusted penalty amount imposed as provided by 31 U.S.C. Sec. 3729(a) and not more than the greater of twenty-one thousand nine hundred sixteen dollars or the maximum inflation adjusted penalty amount imposed as provided by 31 U.S.C. Sec. 3729(a), plus three times the amount of damages which the government entity sustains because of the act of that person.

RCWA 74.66.020.

132. For purposes of the Washington State Medicaid Fraud FCA the terms "knowing," "knowingly," and "material" are defined consistent with the federal FCA. RCWA 74.66.010(7) and (8).

133. In pertinent part, the Washington State Medicaid Fraud FCA defines "claim" as

> any request or demand made for a medicaid payment under chapter 74.09 RCW or other applicable law, whether under a contract or otherwise, for money or property and whether or not a government entity has title to the money or property, that: (i) Is presented to an officer, employee, or agent of a government entity; or (ii) Is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the government entity's behalf or to advance a government entity program or interest, and the government entity: (A) Provides or has provided any portion of the money or property requested or demanded; or (B) Will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded.

Id. at RCWA 74.66.010(1).

134. In addition, RCWA 74.09.240 prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for furnishing any item or service for which payment may be made, in whole or in part, under the Washington Medicaid program.

26. District of Columbia False Claims Act, D.C. Code § 2-381.01, *et seq.*

135. D.C. Code § 2-381.02 provides liability for any person who:

> (1) Knowingly presents, or causes to be presented, a false claim for payment or approval;
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> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

(3) Has possession, custody, or control of property or money used, or to be used, by the District and knowingly delivers, or causes to be delivered, less than all of that money or property;

(4) Is authorized to make or deliver a document certifying receipt of property used, or to be used, by the District and, intending to defraud the District, makes or delivers the receipt without completely knowing that the information on the receipt is true;

* * *

(7) Conspires to commit a violation of paragraph (1), (2), (3), (4), (5), or (6) of this subsection; or

(8) is the beneficiary of an inadvertent submission of a false claim to the District, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the District

… Any person who commits any of the following acts shall be liable to the District for 3 times the amount of damages which the District sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the District for the costs of a civil action brought to recover penalties or damages, and shall be liable to the District for a civil penalty of not less than $5,500, and not more than $11,000, for each false or fraudulent claim.

D.C. Code § 2-381.02.

136. For purposes of the D.C. False Claims Act the terms "knowing," "knowingly," and "material" are defined consistent with the federal FCA. D.C. Code § 2-381.01(7) and (8).

137. In pertinent part, the D.C. False Claims Act defines "claim" as

> Any request or demand, whether under a contract or otherwise, for money or property, and whether or not the District has title to the money or property, that: **(i)** Is presented to an officer, employee, or agent of the District; or **(ii)** Is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the District's behalf or to advance a District program or interest, and if the District: (I) Provides or has provided any portion of the money or property requested or demanded; or (II) Will reimburse the contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded[.]

Id. at § D.C. Code § 2-381.01(1).

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138. In addition, D.C. Code § 4-802(c) prohibits soliciting, accepting, or agreeing to accept any type of remuneration for the following:

(1) Referring a recipient to a particular provider of any item or service or for which payment may be made under the District of Columbia Medicaid program; or

(2) Recommending the purchase, lease, or order of any good, facility, service, or item for which payment may be made under the District of Columbia Medicaid Program.

VI. FACTUAL ALLEGATIONS

A. Mitral Regurgitation and Various Treatment Techniques

139. Mitral Regurgitation ("MR") is a condition that results when the heart's mitral valve fails to close tightly and thereby disrupts blood flow through the heart. MR is often mild, progresses slowly, and people with MR can be asymptomatic for many years. There are two distinct types of MR, degenerative (primary) MR ("DMR") that is caused by structural failure of the mitral valve, and secondary or functional MR ("FMR") that is caused by diseases of the left ventricle. Treatment of MR depends on the severity of the condition, whether it is progressing, and whether there are symptoms. (Source: Mayo Clinic, mayoclinic.org/diseases-condition/mitral-valve-regurgitation/symptoms-causes/syc-20350178.)

140. The gold standard of treatment for patients with DMR is surgical repair or replacement of the mitral valve with a prosthesis. This approach is well-known and accepted in the cardiac care community as it offers a durable treatment with favorable quality of life and survival outcomes. One current surgical technique used to treat DMR involves the use of keyhole incisions on the right side of the chest through the small space between the ribs and then the surgeon can repair or replace the valve, while preserving the stability of the chest, and enabling patients to recover more quickly.

141. A treatment option for FMR involves Guideline-Directed Medical Therapy ("GDMT") developed by specialty societies for the diagnosis and management of heart failure. In addition to lifestyle changes, GDMT involves pharmacological treatment of systolic heart failure and, for eligible patients, implantable cardiac defibrillators, and cardiac resynchronization therapy that can improve symptoms, reduce MR and hospitalizations, and increase survival. [8]

142. GDMT was actually administered to patients as a pre-screening protocol in the Abbott-funded COAPT Trial that was designed to evaluate the safety and effectiveness of TMVR with the MC Device in patients with heart failure and moderate-to-severe or severe FMR. One development from the COAPT trial that Abbott does not discuss in its marketing of the MC Device is that prior to patients being randomly assigned to the MC Device or GDMT study group, many MR patients' symptoms improved so significantly as a result of receiving GDMT in the pre-trial screening phase, that they no longer were eligible for the TMVR procedure and thus, did not enroll in the trial. In fact, management placed constant pressure on the sales team to convince doctors to enroll their patients in the study. Unfortunately, according to a recent study from the CHAMP-HF registry, only 1% of the eligible heart failure population is receiving all of their medications at the recommended doses, which Dr. Paul A. Grayburn, one of the COAPT investigators noted, was "very sad because those drugs reduce your mortality by 30%, and your heart failure, and they're not being used properly. So what we really need is for physicians to recognize that functional MR is a disease of the left ventricle and [that] properly and aggressively treating the left ventricular dysfunction will improve a

[8] CMS National Coverage Decision Memo for Transcatheter Mitral Valve Repair (TMVR)(CAG-00438R). https://www.cms.gov/medicare-coverage-database/details/nca-decision memo.aspx?NCAId=297&bc=AAgAAAAACAAA&

lot of patients in terms of mortality and symptoms."[9] (Source "Super-Responders in COAPT: Improving MR and QoL Is Key, www.tctmd.com/news/super-responders-coapt-improving-mr-and-qol-key). Indeed, despite Abbott's knowledge that many FMR patients on GDMT do improve to the point of no longer being eligible for the MC Device, according to Relator, Abbott's marketing approach for the MC Device was not to provide a fair and balanced presentation of the demonstrated benefits of GDMT but, instead, Abbott targeted referral physicians, and provided them only with the positive results of studies in order to persuade the implanting physicians to engage in "clipping," --*i.e.*, the TMVR procedure using Abbott's MC Device – as the preferred treatment option for their MR patients. By way of example, at Abbott's first TMVR Summit in January 2017, the two keynote physician speakers who presented on the topic of treatment options for MR never even referred to GDMT in their slide deck presentations.

143. The FDA approved TMVR treatment option for DMR (2013) and FMR (2019) actually evolved from a well-known surgical procedure first developed thirty years ago, in 1991, by an Italian cardiac surgeon, Professor Ottavio Alfieri, called "edge-to-edge" repair, or the "Alfieri stitch."[10] Five years after developing this technique, Dr. Alfieri attended a conference in Italy and discussed with a young professor from Columbia University, Dr. Mehmet Oz, his proposal to use only one suture to repair MR. When Dr. Oz, returned to the United States, he and his colleagues at Columbia University decided to use a catheter instead of surgery to insert the suture to close a leak in the mitral valve. Based on this work, in 1997, Dr. Oz submitted a patent application for the device and, in 1999, he created a start-up company called Evalve Inc, which obtained the patent

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[9] "Super-Responders in COAPT: Improving MR and QoL Is Key," www.tctmd.com/news/super-responders-coapt-improving-mr-and-qol-key

[10] Ottavio Alfieri & Paolo Denti, *Alfieri stitch and its impact on mitral clip*, 39 Euro. J. Cardio-Thoracic Surgery 807 (2011).

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and still holds legal title to the patents of the MitraClip. As explained above, Abbott Labs fully acquired Evalve Inc., in 2009 for $410 million dollars. ACS markets and sells the MC Device under an exclusive license from Evalve, Inc, and AVI conducts the marketing, including training to employees regarding MC Device marketing and Speaker Programs for the MC Device.

144. When the MC Device was first approved by the FDA in 2013, it was estimated that less than 5,000 TMVR cases would be performed annually, with approximately 90% of cases billed to Medicare.[11] Six years later, in March 2019, the FDA approved the MC Device to treat patients with FMR. This new indication is expected to broaden the eligible population to as many as 500,000 cardiac patients, thus providing Abbott the opportunity to exponentially increase MC Device sales to billions of dollars.

145. The illegal marketing tactics Abbott has devised to reach this growing population of cardiac patients are at the heart of this Complaint. Through a pervasive nationwide kickback scheme developed by Abbott management and ratified at the highest levels of the Company, Abbott is developing a loyal stable of referring and implanting physicians and hospitals in all states across the country, by providing them with illegal incentives in the form of patient referrals, free patient marketing and support services, lavish meals and cocktail parties, cash honoraria for sham speaker program and patient-practice building events, and lucrative promises to participate in future Abbott medical device studies. In fact, Abbott brags about training and deploying a global workforce to develop "***sales channels and relationships with MitraClip customers, including medical***

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[11] November 14, 2013 Formal Request to CMS for Transcatheter Mitral Valve Repair National Coverage Determination.
https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id273.pdf

1 ***facilities and physicians***"[12] (emphasis added). Moreover, Abbott publicly boasts that its
2 investments in these customer relationships and "its efforts to build a market expected to
3 reach billions of dollars are paying off…," as demonstrated by the recent explosive
4 growth, 26.7%, in MC Device sales in the second quarter of 2019, thus making it a
5 significant source of income for the Company.[13]
6
7 **B. Abbott's Kickback Schemes**

8 146. Abbott's business model for marketing and selling the MC Device revolves
9 around a nationwide kickback scheme involving illegal remuneration to healthcare
10 providers in the form of, *inter alia*, cash honoraria for sham Speaker Programs and
11 events, free meals, lavish cocktail parties and conferences, patient referrals, promises of
12 future rewards, and free patient marketing and promotional services to induce healthcare
13 providers and hospital administrators to perform and grow the TMVR procedure and
14 program, using Abbott's MC Device on cardiac patients covered by Government
15 Healthcare Programs.

16 147. The central aspect of Abbott's kickback scheme involves remuneration to
17 implanting physicians and hospitals in the form of patient referrals and patient practice
18 building nationwide. To carry out its patient referral scheme in all of the states, Abbott
19 targets non-implanting physicians, *i.e.*, physicians who are not certified to implant the
20 MC Device, and induces them through free luncheons, cocktail parties, and dinner
21 conferences to refer their cardiac patients to Abbott's targeted implanting physicians and
22 hospitals for the TMVR procedure using Abbott's MC Device. Abbott also targets
23 implanting physicians and hospitals and provides them with illegal remuneration through,
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25 [12] *See Abbott Cardiovascular Systems, Inc. and Evalve, Inc. v. Edwards Lifesciences*
26 *Corp., et al*, Case 1:19-cv-00149-MN, USDC D. Del, Dkt. 64, p. 14 (emphasis added.)
27 [13] *Id.* at 2, 4.

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inter alia, patient referrals, sham speaker program honoraria, free patient marketing and practice building and promises to participate in future clinical trials, to induce them to use Abbott's MC Device for their cardiac patients.

i. Abbott's Kickback Schemes are Central to their Business Model

148. Abbott's nationwide kickback schemes encompass its entire marketing strategy and were developed by management and ratified by the highest levels of the company. Abbott's President and CEO Robert B. Ford was asked during Abbott's First Quarter 2021 Earnings Call about the progression and trajectory of the MitraClip heading into the second quarter, and he responded " . . . we're making our investments not only on the pipeline side, new versions of MitraClip, ***but also more importantly in the market development, so really to expand the funnel of patients being treated, creating those patient referral networks with the cardiologists on our implanting center. So that's done very well"*** (emphasis added).

149. Management directs Abbott's national sales and marketing team of Therapy Development Specialists ("TDS") (currently called "Market Development Specialists"), Clinical Education Specialists ("CES"), and Account Managers ("AM") on how to approach physicians, develop partnerships with them, and garner their support for and usage of the MC Device through illegal remuneration.

150. For example, in August 2015 at Relator's initial training sessions for new hires, there were sales representatives in attendance whom Abbott hired to market to and for targeted physicians and hospitals in Arizona, California, Connecticut, Florida, Illinois, Indiana, New York, and Ohio. The training for this representative group involved the "MitraClip" messaging tool which offered no disease state information or device instructions but rather was a management composed script outline for the sales representatives to use to convince the implanting physicians that they had "an ideal opportunity to build their patient base from Abbott's referral physicians." In addition, the

new hires received Salesforce data training to educate them about how to use Abbott's national database for referral physician activity planning and tracking the return on investment for their referral activities. Abbott management followed up this training with several conference calls, one in particular in November 2015 hosted by the national Director of Structural Heart Marketing, Tiffany Liu, who used the call to check in with each new employee to make sure they were engaged in best-practices for referral-generating and practice-building activity planning with targeted implanters and referral physicians.

151. In April 2016, Abbott management hosted a National Summit in Chicago for current and newly hired Therapy Development Specialists on the theme of "best practices" for how to effectively target and drive patient referrals from all potential referral sources to implanting physicians and measuring the return on investment from the various practice building activities. These new employees in attendance at the meeting were hired to market to and for physicians and hospitals nationwide including the states of Arizona, Georgia, Illinois, Louisiana, Minnesota, Pennsylvania, Texas, Northern California, Hawaii, and Washington State. Relator's manager asked her/him to give a presentation at this conference about the importance of targeting cardiac surgeons for patient referrals. In following up on this 2016 national meeting, relator's manager Michael Meadors sent out an email to all the management and the West Region: "[i]t's all about 'filling' and 'emptying.' The schematic [funnel diagram] just to the right of our boss [Roach holding the red funnel] is what we, as a management group, believe is fundamental to our short and long-term success." Five years later, Abbott management is still bragging about their continuous marketing efforts and successful execution of their nationwide scheme of expanding the funnel with patient referrals being treated with the MC device at implanting centers.

152. Abbott employees are also evaluated and rewarded based on the number of referrals they successfully secure for their targeted physicians nationwide and the number of MC Device procedures performed by those physicians. While Abbott provides training on the controls it purportedly has in place to prevent such kickback activities, when Relator lodged complaints with Abbott's Office of Ethics & Compliance ("OEC") and Employee Relations Department with specific details about the practice-building activities and kickback scheme, Relator received no response or indication that an investigation would be conducted to address these practices, thus signaling the absence of any meaningful enforcement of Abbott's supposed compliance policies and procedures.

153. Relator's manager, Michael Meadors ("Meadors"), directed the sales team through the kickback scheme and constantly pressured them to host events with physicians to drive up MC Device patient implants. He also met with physicians to make Abbott's expectations in exchange for remuneration clear, and to ensure that physicians knew that they had to refer MC Device patients and/or use the MC Device if they expected future rewards and inducements from Abbott.

154. Abbott's management included their nationwide kickback scheme in almost every aspect of the national sales team's daily jobs. For example, management ranked physicians based on their "market share decile" and their ability to make patient referrals and made it clear to its sales force that credit would only be given to its salesforce in the form of bonuses for those patients who were referred from a specific group of non-implanting physicians and were steered to management-chosen hospitals and were treated by a specific, targeted group of implanting physicians. During a November 12, 2015 meeting that included Abbott Account Manager, Nathan Foreman ("Foreman"), and Meadors, Foreman told Relator that he/she would only get credit for hosting events and activities in connection with targeted account hospitals in Los Angeles, if the patients who were treated with the MC Device were referred from specific referral physicians and

were treated by specific implanting physicians. Relator expressed concern that this approach sounded like "practice-building" – which is well known throughout Abbott, including by Relator and Relator's managers, to constitute a violation of the AKS – and Foreman indicated that he agreed with this conclusion. In response, Meadors abruptly ended the meeting, and shortly thereafter, Relator was informed that Los Angeles was no longer in his/her assigned sales territory.

155. Abbott clearly rewarded its sales representatives based on their ability to successfully build implanting physician practices in all of the states. In an April 25, 2016 email, Meadors sent Relator his/her Q2 2016 Incentive Compensation Calculator and Abbott's Incentive Plan for Therapy Development Specialists. The Incentive Plan included a "Procedure Growth" metric, which evaluated the goal "to grow Implanted MitraClip Procedures in Targeted Accounts." Additionally, in Relator's 2016 Annual Performance Review certified by Meadors, he/she was evaluated under "customer focus" and "leadership" metrics. The "leadership" metric included "[c]ollaborat[ing] strategically with internal customers and external stakeholders to ***build business***" (emphasis added). Relator understood the reference to building business to be code for practice building, based upon the approach that Abbott had devised to drive MC Device sales. The "customer focus" metric included uncovering "underlying customer needs and relentlessly leveraging the best of Abbott Vascular until they are satisfied." Satisfying customer needs was key to Relator's manager's marketing approach. For example, Meadors told Relator that, for two of his/her targeted physicians who were not performing enough procedures with the MC, to increase their usage of the MC Device, that s/he had to do whatever was necessary to please the physicians. These two targeted physicians, RG and DS, as well as the inducements provided to them at Abbott's direction to please (and influence) these physicians are discussed more fully below.

156. In addition, Relator's manager would routinely provide oversight of his/her weekly calendar of the various free luncheons and events that he/she was planning as inducements for specific referring physicians. For example, in August 2016, Meadors confronted Relator for not planning activities for a specific group of referring physicians for a specific implanting hospital (Sharp Hospital in San Diego, California). Meadors openly accused Relator of not "owning the referral," and warned Relator that he/she would need to "own" these physicians to hit Abbott's performance metrics. In response, Relator sent Meadors an email that contained a list of the several "owning the referral" activities that he/she had executed that quarter for specific referring physicians for the specific hospital. On Relator's "owning the referral" list was a free luncheon on July 5, 2016, for referring physician, Dr. B.F., in exchange for potential patient referrals to implanting physician, Dr. R.G.; a free luncheon on August 18, 2016, in exchange for referring physician, Dr. H.H., for potential patient referrals to implanting physician, Dr. H.K.; and for another free luncheon on August 24, 2016, for referring physicians from Chula Vista Cardiology in exchange for potential patient referrals to Dr. H.K.

157. Relator also provided a list of planned, future "owning the referral" physician activities. These future activities included a free luncheon on September 2, 2016, for Metro Family Physicians in exchange for potential patient referrals to implanting physician, Dr. R.G., and a free luncheon for referring physicians, Drs. W.P. and S.G., in exchange for potential patient referrals to Sharp Hospital implanting physicians.

158. Abbott management's "owning the referral" requirement was a key element in Abbott's marketing and sales guidance. Abbott even hosted a full conference in 2016 on owning the referral, the 2016 Abbott Structural Heart Mid-Year Meeting was titled "OWN IT: Lead the Revolution," and featured break-out rooms called, for example,

"Owning the Referral Experience," and "Owning the Power of Data – Zephyr."[14] Six months later, Abbott's Structural Heart General Sales Manager continued to stress Abbott's theme of "owning it". In a February 3, 2017 email following up on Abbott's National Sales meeting, Roach with the subject-line "OWN IT!," the sales team was advised that everyone, regardless of title, "owns" Abbott's marketing development plans to be "primary players in the growth of this group [cardiovascular business patients]." Roach also commented about Abbott's culture, stating, "It's how we engage with our customers and make them our partners in growing their business and best of all, helping them save lives."

159. In addition to providing his/her manager with regular updates about the potential referring physicians who were being provided remuneration to refer patients to targeted implanting physicians at specific targeted hospitals, Relator and his/her sales colleagues were required to enter data about the referring and implanting physicians in Abbott's sales and marketing database, Salesforce.com ("Salesforce"). In fact, procedure tracking was so important to Abbott that they made sure to make Salesforce available at all times, including as an application for employee phones and on employee iPads.

160. For every TMVR procedure using the MC Device, sales representatives were required to provide the name and office of the referring physicians, the name of the implanting physicians who performed the procedure, the number of MC Devices used for each patient procedure, and the name of the hospital where the procedure was performed. Through the Salesforce database tracking tool, Abbott management was able to determine the extent to which its inducements to the referring physicians were paying off in the

[14]A discussion of Zephyr appears below.

form of actual patient referrals to the targeted physicians who were performing the TMVR procedure with Abbott's MC Device.

161. In addition, Abbott's management expected its sales representatives to routinely use this tracking tool to schedule follow-up visits with the referring physicians to thank them for their patient referrals by providing them free lunches, and also to plan future Abbott-hosted events for them with implanting physicians in order to keep the patient referral process active and productive for the MC Device implanting physicians. Abbott management also used this patient referral data to evaluate the sales representative's job performance and to calculate their bonus payments. For example, in an April 29, 2016 email, Meadors presented a "West Region Mapping Scorecard" that contained the Salesforce MC Device procedure data for each CES and was used routinely by Abbott management for the sales team to show which employees were deficient in providing the requisite physician referral information.

162. Abbott also employed the third-party vendor, Zephyr Health ("Zephyr"), to create an application that used Abbott's Vascular Illuminate™ Platform to generate a score for specific data pertaining to targeted healthcare providers, including the physicians' influence, engagement, and claims for MC Device procedures. Every sales representative, manager, and director had access to the Zephyr application and database. Zephyr was designed as a tool for sales representatives to target referring physicians for speaker programs, event planning, and ultimately their patients for MC implanting physicians.

163. Based on Relator's participation in Abbott's National training meetings and National Sales and Management meetings with peers and managers who were marketing to and for physicians and hospitals all around the country, it is clear that Abbott's illegal marketing practices occurred in all states. Here are illustrative examples of physicians who received remuneration from Abbott in the form of, *inter alia*, speaker program

payments, patient referrals, cocktail receptions, free promotional and marketing services, and who were reimbursed by State healthcare programs for the MC implanting procedure performed on cardiac patient beneficiaries.

a. Relator's manager, Michael Meadors, assigned him/her to California implanting physician Dr. S.K. for practice building support services. Mr. Meadors told Relator that Dr. S.K. had a long-standing, important relationship with Abbott, and thus, it was imperative to "keep him happy". Relator quickly learned that Dr. S.K was the top implanting MC implanting physician in the world in terms of volume, and continually driving referrals to Dr. S.K. was one way that Abbott maintained this partnership relationship with Dr. S.K and kept him happy. From 2015 to 2021, Abbott's payments to Dr. S.K. exceeded one million dollars ($1,404,280.64), and from 2013-2020 the State of California (MediCal) reimbursed Dr. S.K. $23,412.22 for the MC TMVR implanting procedure for MediCal covered cardiac patient beneficiaries.

b. On February 28, 2017, Abbott hosted a MitraClip marketing reception at El Camino Hospital for MC implanting physician Dr. CR. The reception was in the guise of a celebration of the 100th MitraClip procedure, and this marketing event was typical of what Abbott management instructed its national sales representatives to organize and host as a "Milestone Celebration" in order to showcase the loyal implanting physicians and their hospitals/medical centers. The physician being celebrated/marketed here was paid over $250,000 by Abbott from 2015 to 2021, and was reimbursed by the State of California (MediCal) over $12,000.00 for performing the MC TMVR procedure on state healthcare program funded cardiac patients from 2013 to 2020.

c. Dr. J.R was a key Florida physician targeted by Abbott management for patient-practice building. One example of Abbott's approach to showing Dr. J.R. the

quid pro quo for his commitment to the MC device was manager Michael Meador's offering Dr. J.R. the opportunity to speak at Abbott's Annual TMVR Summit in 2017. In addition, from 2015-2021, Abbott made payments to Dr. J.R. that exceeded $270,000.00, and the State of Florida Medicaid program reimbursed Dr. J.R. nearly $5,000.00 from 2013 to 2020 for MC TMVR procedure performed on state-funded cardiac patient beneficiaries.

d. Another example of Abbott's illegal marketing practices in Florida involved assisting Dr. R.Q. for patient-practice building. The sales representatives assigned to Dr. R.Q., Michelle Butler and Scott Reynolds, were specifically directed by their manager Frank Sobczak to target Internal Medicine physicians for referrals to MitraClip targeted implanters because many internists and family practice physicians in Florida referred directly to interventional cardiologists and performed the screening procedures that clinical cardiologists do in other states. From 2015 to 2021, Dr. R.Q. received over $300,000 in payments from Abbott, and from 2013 to 2021 was reimbursed by the State of Florida Medicaid program nearly $14,000.00 for performing the MC TMVR procedure on state government-funded cardiac patient beneficiaries.

e. Abbott's sales representative, Linda Morgan, who marketed to and for physicians in the Northeast, Connecticut and New York in particular, was selected by management to present at Abbott's April 2016 National Sales meeting on the topic "Implanter Driven Programs." The meeting was attended by the National Sales Director, Abbott managers representing all the states in the U.S., the U.S. Marketing Management team, as well as all of the Therapy Development Specialists. In her presentation, Ms. Morgan advised the attendees to focus their initial outreach for referrals in local medical centers "with 'in-reach.'" She also identified three medical centers where she focused her referral outreach efforts and noted her success at

obtaining referrals from each location over the past three months, including Montefiore Medical Center with 3 referrals, NorthShore University Medical Center with 5 referrals, and NYU with 14 referrals. In addition, Ms. Morgan trained the new hires, and with great specificity, instructed them about how she successfully executed referral events for targeted physicians. For an example of a best practice activity, to grow targeted implanting physician Dr. G.T.'s patient base, Ms. Morgan explained how she coordinated with marketing directors at various medical facilities to plan an "Over 55 Community Event" where Dr. G.T. could meet prospective patients and referring physicians. Ms. Morgan also explained how she would schedule dates for Dr. G.T. to attend Grand Rounds at neighboring hospitals for potential patient referrals. From 2015 to 2021, Abbott made payments to Dr. G.T. exceeding $200,000.00, and from 2013 to 2020 the State of New York Medicaid program reimbursed Dr. G. T. nearly $5,000.00 for performing the MC TMVR procedure on state government-funded cardiac patient beneficiaries.

f. Abbott also provided free marketing and patient practice building for New York implanting physician Dr. S.K. in the form of a free reception and speaker program on April 11, 2016 and the opportunity to meet referring physicians at the trendy Barcelona Wine Bar in Stamford, CT. From 2015-2021, Abbott made payments to Dr. S.K. that exceeded $186,000.00, and from 2013 to 2020, the State of New York Medicaid program reimbursed Dr. S.K. nearly $12,000.00 for the MC TMVR procedure performed on cardiac patients covered by New York state government healthcare programs.

g. Abbott provided free marketing for its targeted New York physicians with a cocktail reception and dinner program on April 12, 2016 at the Amali Restaurant for Dr. N.P and Dr. C.K. with a program entitled, "New Treatment Frontiers For Mitral Valve Disease." A ruse Abbott used to assist implanting physicians grow their

patients through referrals was a template, generic letter directed to referral physicians that Abbott created for Dr. C.K. with Dr. C.K.'s hospital logo making it appear as if it were the hospital's stationery and letter from the physician, not an Abbott template letter to potential referring physicians. Abbott paid Dr. C.K. over $52,000.00 from 2015-2021 and the New York State Medicaid program reimbursed Dr. C.K. over $7,000.00 from 2013 to 2020 for performing the MC TMVR procedure on New York state government-healthcare funded cardiac patients. This outright marketing and public relations support and assistance to the physicians and hospital's cardiac program by an Abbott representative is yet another way Abbott provided valuable services and resources to their MitraClip physician partners in growing and building their business and practices all with the understanding and expectation they would be treating patients with the MitraClip.

h. Abbott hosted a National Sales Meeting in Denver and paid Georgia implanting physician Dr. V.R. to speak to Abbott's national sales force. The theme of the conference was Abbott's marketing strategies about owning the customer, "OWN IT: Lead the Revolution." Abbott's management and sales team from all over the country treated Dr. V.R. to a full display of Abbott's culture of engaging with the physician customers, and making them partners in growing their business. From 2015-2021, Dr. V.R. received monetary payments from Abbott exceeding $270,000.00 and from 2013 to 2020, he was reimbursed by the State of Georgia over $4,000.00 for performing the MC TMVR procedure on cardiac patients covered by the state healthcare program.

164. During his/her employment at Abbott, Relator reported his/her concerns about Abbott management's behavior and practice-building activities to the Human Resources Department, Sales Department, and Office of Ethics and Compliance, but never received

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a response or acknowledgement about what, if any, investigation Abbott conducted regarding his/her concerns.

ii. Abbott Partners with Physicians to Promote the MC Device

165. Abbott identifies and develops partnerships with targeted implanting physicians and hospitals nationwide, providing them with illegal remuneration in exchange for using the MC Device for TMVR procedures. Abbott expects its employees to develop "business relationships" with these physicians. Relator's manager expected the sales team to "work on forming closer relationships with the implanters" and to "truly partner with [Abbott's] administrative and clinical champions." In order to do so, Abbott required its sales representatives to organize and pay for multiple lavish luncheons and dinners for targeted implanting physicians to build those relationships and induce them to use the MC Device. Relator was directed by Meadors to arrange "intimate gatherings" for these events, contrary to Abbott's own OEC policy requiring a "business appropriate venue conducive to holding business discussions" for physician meals. What was important was that the sales team do what was necessary to please the physicians and form lasting partnerships. Abbott's relationships with these physicians implicates the AKS because physicians are required to treat their patients based on their own independent medical judgment without compromising patient medical needs as the result of inducements received from medical device companies such as Abbott.

166. Forming partnerships with the physician involved providing practice-building support and aiding them in growing their businesses. To that end, Abbott targets non-implanting physicians who have cardiac patients and directs its sales team to provide these targeted "referring physicians" with free luncheons, cocktail hours, and dinner conferences with the goal of inducing them to refer their patients to chosen implanting physicians for the TMVR procedure using the MC Device.

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167. An example of a management tactic Abbott used to push sales representatives to get patient referrals for the implanting doctors was called "Fill and Empty the Funnel." Abbott's National Sales Director, Roach, would carry a large red funnel to sales meetings and repeat the phrase "fill and empty the funnel" tirelessly to instruct Abbott's sales and marketing team about how to promote Abbott's MC Device: the team had to "fill the funnel" with patients referred by non-implanting physicians who were induced to refer with free meals, cocktail parties, and lavish dinner events; then they had to "empty the funnel" by inducing implanting physicians with the same tactics to treat the referred patients with the MC Device.

168. According to Meadors, Abbott firmly believed that inducing referral physicians to fill the funnel with their referred patients and convincing physicians to empty the funnel by treating the referred patients with the MC Device was critical to Abbott's success in promoting the MC Device. In an April 5, 2016 email regarding Abbott's best sales and marketing practices and priorities, Meadors instructed his team that "[i]t's all about 'filling' and 'emptying.' The schematic [funnel diagram] just to the right of our boss [Roach holding the red funnel] is what we, as a management group, believe is fundamental to our short and long-term success." One month later, Meadors sent a follow up email reinforcing Abbott management's expectation that his team "leverage their individual strengths all while keeping to the organizational direction of 'funnel filling and funnel emptying' – with AMs and TDS filling by driving patients from the periphery to treatment centers, and with CESs emptying by owning valve coordinator relationships, raising awareness and driving optimization which will increase throughout the treatment center (will also increase new patients to be treated)."

169. Abbott's management expected sales personnel to fill and empty the funnel through the use of illegal kickbacks. For example, Relator was expected to host at least 15 events for patient referral physicians during the second, third, and fourth quarters of

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2016. In Abbott's "2Q16 Structural Heart Quota and Compensation Rollout: Therapy Development Specialists," the entire TDS team was required to individually host at least six events in the second quarter, at least nine events in the third and fourth quarters in the first quarter for a total of 15 Abbott-sponsored physician events.

170. The following are illustrative examples of instances in which Relator was required to provide inducing meals that were primarily social in nature to referring physicians with no legitimate business purpose as part of the marketing services that Abbott undertook on behalf of the MC device implanting physicians in order to build their practices in violation of the AKS:

A. October 23, 2015 marketing lunch ($376.04) for the California Cardiac Institute, specifically targeting the main physician of the practice, Dr. D. W.L., a high-decile cardiologist, to refer his cardiac patients for the MitraClip procedure to implanting physicians Dr. S.B. at Good Samaritan Hospital in LA and Dr. S.K. at Cedars-Sinai in Beverly Hills, CA.

B. October 31, 2015 The Promiscuous Fork restaurant ($108.96) marketing lunch Relator brought to cardiac surgeon Dr. J.T., the referring physician in reward for a patient who received the M.C. Device on 10/29/15 from Relator's targeted implanting physician Dr. M.P..

C. November 6, 2015 marketing lunch ($264.54) that Relator brought to San Diego Cardiology Associates, whose cardiac care patients Abbott targeted for referrals to assist in building the patient practice for MC Device implanting physician Dr. M.P.

D. January 7, 2016 Luna Grill ($183.30) marketing lunch that Relator brought to Dr. J.H., a potential referral doctor for MC Device implanting physician Dr. M.P. Following this lunch, Relator made arrangements for a dinner meeting for Drs. J.H. and M.P. to further market the practice of Dr. M.P.

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E. January 12, 2016 marketing dinner ($855.35) at Flemings Steakhouse in Chandler, AZ. Relator was instructed by his/her manager to organize for Dr. H.N. in building his patient practice for MC Device procedures with a group of referring doctors from Gilbert Cardiology. Attending the dinner with Relator was Abbott Account Manager Michael Quinn, and Abbott Clinical Education Specialist Susan Jordan. As reflected on the receipt, wine and martinis were served at the dinner.

F. January 12, 2016 marketing lunch ($207.12) that Relator brought to a group of cardiologists who were being targeted for patient referrals for MC Device implanting physician Dr. A.P.

G. January 14, 2016 Citizens Public House ($379.75) marketing dinner Abbott hosted for cardiologist Dr. A.A., considered by Abbott to be an "Access" for patient referring physicians to meet and socialize with MC Device implanting physician Dr. A.P. with the goal of inducing Dr. A.A. to funnel/refer his patients with MR to Dr. A.P. for Abbott's MC Device procedure.

H. February 4, 2016 Seasons 52 restaurant ($259.23) marketing dinner Abbott hosted for "Access" by patient referring cardiologist Dr. A.M. to meet and socialize with MC Device implanting physician Dr. A.P. with the goal of inducing Dr. A.M. to funnel/refer his patients with MR to Dr. A.P. for Abbott's MC Device procedure.

I. March 7, 2016 ($353.31) marketing lunch to Escondido Cardiology, a medical practice that includes Dr. R.S., an interventional cardiologist and MC Device "Access Physician" for possible patient referrals/funneling to Sharp Memorial's MC Device program.

J. March 10, 2016 Pamplemousse Grille ($687.52) marketing dinner Abbott hosted for patient referring physician Dr. M.M. and implanting physician Dr. M.P. with the goal of inducing Dr. M.M. to funnel his patients with MR to Dr. M.P. for the MC Device. Relator and Abbott Clinical Education Specialist Rafid Haddad hosted

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the dinner, and with the expensive alcohol and meals, this practice building social event exceeded Abbott's per person meal spend limit.

K. March 11, 2016 marketing ($160.66) lunch for Dr. T.D. and his practice. Dr. T.D. is a patient referring cardiologist for Dr. M.P.'s MC Device practice. As shown in Relator's Salesforce records, Dr. T.D. referred a patient for a MitraClip procedure that Dr. M.P. performed a month earlier, on 2/4/16.

L. March 21, 2016 marketing lunch ($294.34) for Dr. D.C.'s practice for his patient referrals as well as to check about future referrals for Abbott-targeted MC implanting physician, Dr. M.P. As seen in Relator's Salesforce records, Dr. D.C. referred the patient for the MC Device procedure performed by Dr. M.P. on 12/8/15.

M. March 22, 2016 Luna Grill marketing lunch ($173.36) for Dr. G.F. and his practice. He is a cardiologist affiliated with both Scripps and Sharp healthcare system and who was targeted by Abbott to funnel/refer his patients to MC implanting physician, Dr. M.P..

N. March 24, 2016 Mister A's receipt for $452.86 for a marketing dinner Abbott hosted for potential patient referring thoracic surgeon, Dr. J.H. to meet Abbott-targeted implanting physician, Dr. M.P. The purpose of this dinner was to encourage Dr. J.H. to refer his MR patients who are non-surgical candidates to Dr. M.P. for the MC Device procedure.

O. April 13, 2016 Flemings Restaurant marketing dinner (over $1,000) that Abbott hosted for MC implanting physician, Dr. M.P. and cardiac surgeon and potential patient referring physician Dr. S.B.[15]

P. May 24, 2016 marketing lunch ($496.79) Relator brought to Scripps Integrative Medicine (SIM), a large cardiology clinic consisting of referring

[15]The bill at issue for this meal was manipulated to conceal the full charges in the manner that Relator was taught to do so by Abbott's management.

1 physicians Dr. D.T., Dr. C.S., Dr. E.K. and Dr. J.P.G. At this lunch, implanting
2 physician Dr. M.P. spoke about his MC Device program, and as reflected in Abbott's
3 Salesforce records, both Dr. D.T. and Dr. J.P.G. referred patients to Dr. M.P. for MC
4 Device procedures on 4/8/16 and 9/2/15 respectively.

5 Q. June 6, 2016 marketing lunch ($181.14) for lunch for Cardiology Specialists
6 Medical Group (CSM), whom Dr. M.P. specifically requested that Abbott target to
7 refer patients to him for the MC Device procedure.

8 R. June 7, 2016 marketing lunch ($234.00) for cardiologist Dr. K.L.'s practice
9 to refer patients to Abbott for targeted MC implanting physician, Dr. M.P.

10 S. June 9, 2016 marketing lunch ($150.14) for Dr. N.S. and Dr. S. for potential
11 patient referral physicians for Abbott-targeted MC implanting physician, Dr. M.P.,
12 who requested that Abbott assist him in building his practice in the Temecula
13 Valley/Murrieta (CA) area where these potential referral physicians are located.

14 T. August 31, 2016 marketing lunch ($265.77) hosted by Relator and Rafid
15 Haddad for Dr. J.G., the Medical Director for the Department of Cardiology at Scripps
16 Mercy Hospital. The purpose of the meeting was to discuss patient referrals to Dr.
17 M.P. for the MC Device procedure.

18 U. September 8, 2016 marketing lunch ($355.20) for the Scripps Clinic Carmel
19 Valley Cardiology practice consisting of referring cardiologists Dr. T.H. and Dr. P.H.
20 to Abbott-targeted MC implanting physician, Dr. M.P. As reflected in Abbott's
21 Salesforce records, Dr. P.H. referred a patient to Dr. M.P. for a MC Device procedure
22 on October 7, 2015.

23 171. In other words, rather than marketing the MC Device to physicians and
24 hospitals that might utilize the MC Device in procedures through legitimate marketing
25 based upon education of implanting physicians and hospitals, Abbott built its entire
26 marketing strategy on bribing referring physicians, hospitals and physicians implanting
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1 the MC Device through free expensive meals and other inducements in order to obtain
2 referrals for the implanting physicians and hospitals. And, once physicians began
3 implanting, Abbott bribed those physicians to encourage and induce their continued use
4 of the MC Device. In other words, Abbott's marketing of the MC Device is focused
5 almost entirely on offering inducements designed to market and support the practices of
6 physicians who implant the MC Device and then handsomely rewarding the implanting
7 physicians who participate in Abbott's scheme. It is well established that, when a
8 medical device manufacturer devotes its resources to developing the practices of
9 physicians (here the implanters of the MC Device), such conduct violates the AKS, FCA
10 and analogous state laws. DeLaurentis, Hooker and DePrince, *Anti-Kickback Statute*
11 *Enforcement Year in Review and Outlook for 2021*, https://www.jdsupra.com/legalnews/
12 anti-kickback-statute-enforcement-year-5333044/ (March 25, 2021)("Practice Building
13 and Support -- In addition to patient inducements, another continued focus for AKS
14 enforcement is remuneration provided to physicians and practices in exchange for
15 practice building and practice support. In 2020, DOJ recovered at least $30,000,000 in
16 settlements from medical device manufacturers and biotechnology companies that
17 allegedly provided support to physician practices and hospitals that were intended to
18 induce or reward use of their products"); Beimers & Melvin, *Kickback and Stark Law*
19 *Developments,* Healthcare Enforcement Compliance Institute https://assets.hcca-
20 info.org/Portals/0/PDFs/Resources/Conference_Handouts/Healthcare_Enforcement/2015/
21 P6_KickbackandStarkLaw_3slides.pdf (October 25, 2015)(noting that recent
22 enforcement priorities by the Department of Justice have been focused on "Physician
23 Practice Building" and that the "Government has taken the position that joint marketing
24 arrangements may provide improper inducement," including "Physician-led patient
25 seminars[,] Physician referral events[,] Practice assessments[,] Co-branding[,] and
26 Cooperative Advertising"); *Covidien to Pay Over $17 Million to The United States for*
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Allegedly Providing Illegal Remuneration in the Form of Practice and Market Development Support to Physicians, https://www.justice.gov/opa/pr/covidien-pay-over-17-million-united-states-allegedly-providing-illegal-remuneration-form (March 11, 2019)("The practice and market development support Covidien provided included customized marketing plans for specific vein practices; scheduling and conducting 'lunch and learn' meetings and dinners with other physicians to drive referrals to specific vein practices; and providing substantial assistance to specific vein practices in connection with planning, promoting, and conducting vein screening events to cultivate new patients for those practices".)

172. This practice-building remuneration scheme is key to Abbott's inducement of implanting physicians. The sales team even received training on how to drive patient referrals to implanting physicians at an internal April 2016 Implanter Driven Programs presentation. The goal was to present Abbott as a close partner for these physicians, helping them to build their practices in exchange for performing the TMVR procedure with MC Devices.

173. In fact, Relator was advised by Meadors in a March 8, 2016 Field Visit Memo that he "[had] no desire to support [Relator] wasting [his/her] time or [Abbott's] money on programs who aren't interested in growing" and that, accordingly, Relator should continue to "drive awareness for those who want access to more patients." This included focusing more on Relator's key targeted physicians. In Meadors' subsequent May 4, 2016 Field Visit Memo for Relator, he praised him/her for successfully developing a "partnership" with Dr. M.P. (see below) and focusing on previous referrers.

174. One of Relator's key targeted physicians with whom s/he was expected to build a partnership was Dr. M.P., a San Diego interventional cardiologist who specializes in structural heart procedures. One of the tactics Relator was expected to use to build a partnership with Dr. M.P. was through speaker programs and events. For example, in

February 2016, Relator was instructed by management to host a dinner event for Dr. M.P. at Fleming's Prime Steakhouse and Wine Bar in Palm Desert with local referring physicians because Dr. M.P. was interested in growing his practice in that area. Relator also arranged a dinner in Temecula, CA on May 24, 2016 because Dr. M.P. wanted to solicit patient referrals from that area. In addition, Relator hosted a lunch on June 9, 2016 in the Temecula Valley/Murrieta, CA area for Dr. M.P, and a lunch on June 6, 2016 with the Cardiology Specialists Medical Group (CSM), whom Dr. M.P. specifically requested that Abbott target to refer patients to him. These speaker programs and luncheons that Relator hosted for Dr. M.P. offered him a generous fee in the form of a "speaker honorarium," and also offered him an unparalleled opportunity for free marketing and advertising of his services to potential referring physicians in order to build his patient practice. In fact, Relator was instructed to emphasize to his/her targeted implanting physicians that they have an ideal opportunity to build their patient base from Abbott's referral physicians, and that they should "solicit eligible patients from external referral sources such as cardiovascular surgeons, heart failure specialists, and clinical cardiologists."[16]

175. Abbott management made sure that Dr. M.P. understood what Abbott expected for his contribution to the partnership – that is, what Abbott expected from him in return for Abbott's assisting him in building his patient practice. Relator's manager, Meadors, was Abbott's messenger, and he met with Dr. M.P. in August 2016 to explain the three core requirements that Abbott expected from its implanting physician partners: to increase the number of patients treated with the MC Device; to advocate for treatment with Abbott's MC Device; and to obtain patients referred from non-implanting physicians. Meadors summarized Abbott's three expectations in his August 3, 2016

[16]This advice is provided by Abbott's official MitraClip© U.S. Messaging Tool.

follow-up email to Dr. M.P., in which he provided the "take-aways" from the meeting they had the prior day. First, Meadors assured Dr. M.P. that "Your MitraClip program continues to steadily improve (right at the 50 patients treated threshold-…)." Meadors then instructed Dr. M.P. that "getting to advocacy requires an urgency to treat on your part and an urgency to refer from the non-MitraClip implanting physicians." Finally, Meadors closed his email by continuing the theme about Abbott's expectation that they have a productive business relationship in promoting Abbott's MC Device, telling Dr. M.P. that he looked "forward to partnering more closely with [him]."

176. In fact, Dr. M.P. received several thousand dollars from Abbott in the form of cash for speaker program honoraria and lavish meals. Abbott also provided him with other valuable remuneration in the form of patient referrals, as well as free patient marketing and promotional support in an effort to build his patient practice for the MC Device procedure.

177. According to Abbott's own patient referral data from Salesforce, these inducements to Dr. M.P. appear to have paid off well for his patient practice-building and Abbott's MC Device sales. By way of example, in the nine months from July 2015 to March 2016, Dr. M.P. performed the TMVR procedure using the MC Device on at least 20 new patients from the referring physicians that Abbott targeted and provided inducements to make patient referrals to Dr. M.P.

178. Abbott also assigned Relator two implanting cardiologists in Arizona, Drs. H.N. and A.P., and expected him/her to assist them in building their patient practices. Through speaker programs and events Relator hosted for these physicians, Relator believes that Dr. H.N. received several thousand dollars from Abbott in the form speaker program honoraria and lavish meals, and more than $30,000.00 from Medicare reimbursement payments for performing the TMVR procedure on at least four patients from December 2015 to March 2016 from referring physicians whom Abbott targeted

and induced with free meals to make these patient referrals to Dr. H.N. For example, Relator arranged a lavish dinner event with alcohol for Dr. H.N. and potential referral physicians at Fleming's Prime Steakhouse and Wine Bar on January 12, 2016. Following this event, Dr. H.N. performed at least eight TMVR procedures in roughly two and a half months.

179. In addition to funds Dr. H.N. received from Medicare, St. Joseph's Hospital and Medical Center in Phoenix, Arizona, where Dr. H.N. performed the TMVR procedure, obtained Medicare reimbursements of approximately $1,000,000.00 for the TMVR procedures, including the cost of the MC Device. Dr. H.N. also presumably received additional remuneration as a result of driving this business to St. Joseph's Hospital and Medical Center.

180. Relator's other Arizona targeted implanting physician, Dr. A.P., also benefitted greatly from Abbott's inducements: Dr. A.P. received several thousand dollars from Abbott in the form of speaker program honorarium and meals, and he has received more than $100,000.00 from Medicare reimbursement payments for performing the TMVR procedure using Abbott's MC Device on at least 18 patients from May 2015 to April 2016; these patients were referred from physicians who were targeted by Abbott and induced through free meals to make said referrals. In addition, even though there was another implanting physician at Dr. A.P.'s hospital, Relator's sales performance was only evaluated based on steering patients to Dr. A.P.'s practice because Abbott was focused on building Dr. A.P.'s patient practice so that Dr. A.P. would use Abbott's MC Device to treat these new patients, thus increasing MC Device sales for Abbott.

181. In addition to reimbursing Dr. A.P., Medicare also reimbursed the hospital where he performed the TMVR procedure, Banner University Medical Center in Phoenix, Arizona, more than $3,000,000 for the TMVR procedures, including the cost of the MC Device. Banner University Medical Center also benefitted from secondary

procedures and other additional procedures that would be required for the referred patients' care at the hospital.

182. The below chart provides a sample of the MC Device procedures for Relator's implanting physicians from referral physicians that Abbott tracked using the Salesforce database. Relator calculated that Dr. M.P. and his hospital have received approximately $1,209,900.00 in combined reimbursement for the MC Device and procedure for these referred patients from 2015-2016. For Dr. H.N. and his hospital, the amount is $323,000.00 over same period, and for Dr. A.P. and his hospital, the amount is $840,100.00. For a representative sample of false claims based on CMS physician and hospital Medicare estimated reimbursement amounts for the TMVR procedure and MC Device, and Abbott's payments[17] to the implanting physicians, please see **Exhibit A**. For a representative sample of false claims based on State Medicaid physician reimbursement payments for the TMVR procedure, and Abbott's payments[18] to the implanting physician, please see **Exhibit B**.

Date of Procedure	Implanting Physician	Referring Physician	# of Mitra Clips	Abbott Proctoring Representative[19]
7/2/2015	Dr. M.P.	Dr. D.K.	3	Haddad, Rafid
7/24/2015	Dr. M.P.	Dr. K.S.	1	Haddad, Rafid
8/6/2015	Dr. M.P.	Dr. K.S.	1	Haddad, Rafid
9/2/2015	Dr. M.P.	Dr. J.P.G.	2	Haddad, Rafid
10/7/2015	Dr. M.P.	Dr. P.C.H.	2	Haddad, Rafid

[17] Abbott's payments to physicians include general payments, such as speaker honorarium, consulting fees and meals, and associated research funding payments, including, for example, Abbott's payments to the COAPT trial investigators.
[18] Abbott payments to HCPs are for the CMS open payments reportable time period of 2015-2021. State Medicaid Payments to HCP for TMVR procedure are for the reportable time period of 2013-2020.
[19] Proctoring Representative refers to the Abbott Vascular sales division employees who attended the procedures for implanting the MC Device.

Date of Procedure	Implanting Physician	Referring Physician	# of Mitra Clips	Abbott Proctoring Representative[19]
10/16/2015	Dr. M.P.	Dr. V.A.	1	Haddad, Rafid
10/16/2015	Dr. M.P.	Dr. V.A.	1	Haddad, Rafid
10/27/2015	Dr. M.P.	Dr. D.W.L.	2	Haddad, Rafid
10/29/2015	Dr. M.P.	Dr. J.T.	2	Haddad, Rafid
11/6/2015	Dr. M.P.	Dr. R.L.S.	2	Haddad, Rafid
11/24/2015	Dr. M.P.	Dr. D.K.	2	Haddad, Rafid
11/24/2015	Dr. M.P.	Dr. H.K.	2	Haddad, Rafid
12/8/2015	Dr. M.P.	Dr. D.C.	2	Haddad, Rafid
12/18/2015	Dr. M.P.	Dr. A.R.	2	Haddad, Rafid
1/8/2016	Dr. M.P.	Dr. R.P.	2	Haddad, Rafid
1/8/2016	Dr. M.P.	Dr. L.M.	1	Haddad, Rafid
2/4/2016	Dr. M.P.	Dr. T.E.D.	2	Haddad, Rafid
2/16/2016	Dr. M.P.	Dr. H.K.	2	Haddad, Rafid
2/22/2016	Dr. M.P.	Dr. D.K.	2	Haddad, Rafid
2/22/2016	Dr. M.P.	Dr. A.R.	1	Haddad, Rafid
2/26/2016	Dr. M.P.	Dr. T.S.A.	1	Haddad, Rafid
3/25/2016	Dr. M.P.	Dr. S.E.	2	Haddad, Rafid
3/25/2016	Dr. M.P.	Dr. J.V.	2	Haddad, Rafid
4/8/2016	Dr. M.P.	Dr. D.T.	2	Haddad, Rafid
4/8/2016	Dr. M.P.	Dr. M.P.[20]	2	Haddad, Rafid
12/17/2015	Dr. H.N.	Dr. J.H.	1	Quinn, Michael
2/17/2016	Dr. H.N.	Dr. D.S.	1	Jordan, Susan
3/23/2016	Dr. H.N.	Dr. K.D.	2	Jordan, Susan
3/30/2016	Dr. H.N.	Dr. M.G.	1	Jordan, Susan
5/14/2015	Dr. A.P.	Dr. P.K.A.	2	Jordan, Susan
6/11/2015	Dr. A.P.	Dr. M.P.	1	Jordan, Susan
8/27/2015	Dr. A.P.	Dr. J.S.	2	Jordan, Susan
9/17/2015	Dr. A.P.	Dr. R.D.	2	Jordan, Susan
9/21/2015	Dr. A.P.	Dr. S.A.	2	Jordan, Susan
10/29/2015	Dr. A.P.	Dr. A.A.	2	Jordan, Susan
11/2/2015	Dr. A.P.	Dr. A.A.	2	Jordan, Susan
11/19/2015	Dr. A.P.	Dr. S.A.	1	Jordan, Susan
12/1/2015	Dr. A.P.	Dr. W.S.	1	Jordan, Susan
12/3/2015	Dr. A.P.	Dr. A.P.[21]	2	Jordan, Susan
12/10/2015	Dr. A.P.	Dr. G.K.	3	Quinn, Michael
12/28/2015	Dr. A.P.	Dr. A.A.	1	Jordan, Susan
1/7/2016	Dr. A.P.	Dr. S.A.	2	Jordan, Susan

[20] This referring physician is not the same individual as the implanting physician.
[21] This referring physician is not the same individual as the implanting physician.

Date of Procedure	Implanting Physician	Referring Physician	# of Mitra Clips	Abbott Proctoring Representative[19]
1/11/2016	Dr. A.P.	Dr. S.A.	1	Jordan, Susan
1/14/2016	Dr. A.P.	Dr. R.G.	2	Jordan, Susan
2/4/2016	Dr. A.P.	Dr. A.M.	2	Quinn, Michael
2/15/2016	Dr. A.P.	Dr. H.Y.	2	Jordan, Susan
3/14/2016	Dr. A.P.	Dr. S.H.	1	Jordan, Susan
3/24/2016	Dr. A.P.	Dr. S.B.	3	Jordan, Susan
3/31/2016	Dr. A.P.	Dr. K.L.	2	Jordan, Susan
4/1/2016	Dr. A.P.	Dr. M.S.	3	Quinn, Michael

183. Abbott also targeted hospital administrators of the implanting site hospitals and offered inducements to them to encourage their support in providing catheter lab rooms, tech support teams, and valve coordinator staffing, as well as their commitment to growing the TMVR procedure using Abbott's MC Device. Abbott has paid hundreds of thousands of dollars to implanting hospitals in the form of consulting fees, free meals, space rental, and facility fees.

184. During his/her employment at Abbott, Relator was required to invite hospital administrators to free lunches and dinners, including to the lavish 2017 TMVR Summit (described below), in order to promote their support of the MC Device implanting procedure. Moreover, Abbott provided free marketing and promotional support, as well as highly-valued patient referrals, to these implanting hospitals that receive Medicare reimbursement payments, not only for the TMVR procedure, but also for ancillary testing and secondary treatment procedures associated with the MC Device.

185. Abbott understands keenly the so-called "halo effect" that is created when meals, drinks and other entertainment are provided to physicians and how such inducements can affect the behavior of physicians. Indeed, one recent study found that even a single free meal can boost the likelihood that a physician will prescribe a certain drug. *See* DeJong, Aguilar Tseng, Lin, Boscardin and Dudley, *Pharmaceutical Industry–*

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Sponsored Meals and Physician Prescribing Patterns for Medicare Beneficiaries, JAMA Internal Medicine, https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2528290 (August 1, 2016); *see also* Loftus, *Even Cheap Meals Influence Doctors' Drug Prescriptions, Study Suggests*, https://www.wsj.com/articles/even-cheap-meals-influence-doctors-drug-prescriptions-study-suggests-1466434801 (Wall Street Journal, June 30, 2016). Here, as detailed above, Abbott offered physicians much more than inexpensive meals as inducements. Indeed, Abbott set its prescribed limits for reimbursement for meals spent on physicians (which limits themselves were regularly honored in the breach and evaded pursuant to Abbott's own corporate policies) at levels such that it could provide expensive and inducing meals to referring and implanting physicians, even when it chose to abide by its own weakly enforced policies with respect to such meals.

186. Abbott also required its sales and marketing team to pitch hospital administrators about these illegal inducements, as demonstrated in its training and messaging tools. By way of example, Relator was instructed to encourage hospital administrators to support the TMVR procedure using Abbott's MC Device by explaining, through a set script, that the MC therapy offered unparalleled marketing growth and opportunity to remain highly competitive, "Implementing TMVR with MitraClip therapy into an established structural heart program can maintain your competitive edge and provide significant benefits to your institution:

- Enhance the reputation of your structural heart program and demonstrate your commitment to your community
- Clearly differentiate your hospital from competitors by offering the full spectrum of treatment options
- Attract new patients from outside your local community

- Create growth opportunities through profitable procedures, ancillary tests, and referral streams generated by TMVR screenings."

187. At all pertinent times, Abbott engaged in the sales practices and violations of the AKS and FCA detailed in this Complaint throughout the United States in a pervasive manner reflecting the fact that the policies and practices challenged herein were approved and ratified at the highest levels of the Company.

188. In fact, from 2014-2017, Medicare reimbursed hospitals approximately $227 million for the MC Device and costs associated with the TMVR procedure.

189. Another important aspect of the practice-building scheme is involvement in Abbott's clinical trials. For the physicians, clinical trials represent an opportunity to secure funding, prestige, and additional patients – especially because Abbott has even more incentive to funnel patient referrals to those physicians who are involved in one of their trials. Being the site of a clinical trial is a huge draw for hospitals and therefore benefited hospital administrators as well. These trials are also hugely important to Abbott, as they are the method through which Abbott can validate the MC Device and push for greater CMS coverage. As the MC Device was coming to market, it was therefore important for Abbott to ensure that their trial physicians were "kept happy" and supplied with a substantial flow of patients.

190. Abbott used these clinical trials not only to continue to promote the MC Device through partner physicians, but also to secure the physicians' loyalty to using Abbott's device. Indeed, Abbott specifically promised physicians who were implanting MC Devices that they would be part of future clinical trials conducted by Abbott with respect to future products if they maintained their loyalty to the MC Devices.

191. Abbott management also expected the sales team to check in regularly with their targeted implanting physicians and hospitals and offer to host free events and

provide free marketing and promotional support to build their patient base and practice. These "bonus" services were meant to deepen their partnership and make it easier for physicians and hospitals to attract more business.

192. Some of the marketing tactics that Abbott provides to its partner physicians are more subtle. For example, Abbott management – Meadors and Executive Account Manager John Rupp – came up with the idea to issue a "thank you" email to all attendees of Abbott's 2017 TMVR Summit, discussed in Part 2.3. *infra*, that would include a prominent link inviting attendees to "reach out to the local MitraClip team" – which in reality was direct access to Abbott's partnered physicians (Drs. M.P., R.G., R.K., and E.M.). Additionally, the sales team was given letter templates to provide to implanting hospitals and physicians for use with their referring physicians (a means of furthering the referring-implanting relationship and discussing other potential candidates). In similar vein, the 2016 Structural Heart Collaboration HUB program was piloted as an interface for implanting centers to use to manage the referral of patients for the MC Device. These projects were all marketing tactics to assist partner physicians and hospitals to build their practices.

193. Other Abbott marketing tactics were larger in scale. For example, in an August 25, 2016 management discussion with Meadors, Relator was instructed to meet with two of his/her targeted implanting physicians, Dr. R.G. and Dr. D.S., in order to "find out what they want" for marketing support. Following Meadors' instructions, Relator met with Dr. R.G., who had recently signed a speaker program contract with Abbott but whose MC patient treatment numbers had been slowing down because, as he told Relator, he was devoting time to launching another cardiac therapy. After repeated attempts to schedule a speaker program for Dr. R.G., Relator was finally able to arrange and execute what was supposed to be an educational speaker program for him on October

27, 2016, at the San Diego office of Metro Family Physicians, a group of family practice physicians who had potential patients to refer to Dr. R.G.

194. This program was typical of Abbott's use of speaker program as a promotional marketing event for Dr. R.G.'s practice and Abbott's MC Device. Abbott paid Dr. R.G. $2,500.00 for this program, a promotional rather than educational program that Relator was required by his/her manager to arrange in order to re-engage Dr. R.G. so that he would continue to use the MC Device to treat his patients. In fact, during Relator's employment at Abbott, Dr. R.G. has received several thousand dollars from Abbott in the form of cash for speaker programs and meals to induce his advocacy of its MC Device.

195. Similarly, at Meador's direction, Relator also reached out to Dr. D.S., an implanting cardiologist in La Mesa, California, to help him build his patient practice by providing free patient marketing and advertising services. The timing of Meador's invitation of assistance was particularly attractive to Dr. D.S. because he had just finished re-modeling his clinic and wanted to have an open house for his referring physicians.

196. Dr. D.S. gave Relator a list of physicians to invite, and per his/her manager's instructions, Relator created the invitation for the event, distributed the invitation in person to everyone on the list, and hired and paid a caterer $808.00 to prepare a sushi cocktail party for Dr. D.S.'s "Open House" on September 30, 2016, which was attended by his personal guests and referring physicians. In fact, 24 of the 70 invitees appear to have been personal guests, despite the fact that Abbott's OEC guidelines state that "spouses or guests of the HCP/Customer are **not** permitted" (emphasis in original). This Abbott-sponsored happy hour event was nothing more than a payment by Abbott to assist Dr. D.S. in building his patient practice with the clear expectation that, in return, he would increase his use of the MC Device. In fact, when Relator informed Meadors that he/she was having issues with arranging the event – particularly due to the excessive

sushi costs – Meadors assured him/her that it was fine and, on September 9, informed Relator that he "[had] a solution for [his/her] sushi thang [*sic*]" and would speak to him/her about it that afternoon. Meador's "solution" was an instruction to Relator to manipulate the final receipts by attributing the excessive meal costs to items that were unrelated to food such as equipment rental and set up charges.

197. Another huge marketing push for Abbott is CMS lobbying, wherein they work with their partner physicians to increase coverage for the MC Device and relevant procedures. This ploy not only opens the market up for Abbott, but it provides physicians with increased reimbursement amounts and new covered procedures to use the MC Device. Of course, Abbott presented CMS victories as another way in which Abbott was advocating for physicians and helping them succeed.

198. For example, in an August 3, 2016 email to Dr. M.P., Meadors mentioned that a key victory in "getting to advocacy" was a recent CMS decision to increase the amount of reimbursement to hospitals and physicians for the TMVR procedure. Regarding the CMS decisions, Meadors adds the comment: "channeling Rod Tidwell from Jerry Maguire." This is clearly a reference the 1996 *Jerry Maguire* scene in which Rod Tidwell shouts at his agent repeatedly, "SHOW ME THE MONEY."[22] With this comparative reference, Meadors is reminding Dr. M.P. that the CMS monetary reimbursement increase in question is one that Abbott worked to bring about for physicians and hospitals, and that it is one way that Abbott is showing Dr. M.P. and his hospital "the money" – *i.e.,* increased financial benefits from CMS for implanting the MC Device in Medicare patients.

199. In fact, Abbott lobbies quite hard for favorable CMS decisions because it is such a beneficial partnership arrangement for both Abbott and the physicians. Abbott

[22] For reference, see the "Show Me the Money" clip: https://www.youtube.com/watch?v=FFrag8ll85w

encouraged their partner physicians to support the MC Device during the comment submission periods for CMS decisions, in exchange for on-going aid in practice-building and for the financial benefit that physicians would receive from greater coverage. Relator was even given a "menu" of prepared supportive comments drafted by Abbott management and instructed to discuss it with physician implanters, valve teams, and hospital administrators over lunches and dinners, with the goal of encouraging them to submit Abbott's prepared comments to CMS.

200. For example, in June 2020, the CMS opened the comment period for the National Coverage Decision ("NCD") for its proposal to expand Medicare coverage for TMVR to include secondary or functional mitral regurgitation (FMR). Of the several hundred comments submitted by physicians and hospital administrators, many of them appear to be the result of Abbott's lobbying efforts, as described prior. In fact, many of the comments that support the most expansive coverage with the least restrictive qualifications were made by physicians who routinely received payments[23] from Abbott, including Dr. M.P. Additionally, a review of these physicians' comments reveals that they contain similar and often the same exact bullet points in the same order, reflective of these physicians having been given prepared comments to post on Abbott's behalf.

201. Among Abbott's partner physicians who submitted positive, repetitive comments supporting the NCD are the following (along with the approximate amount of payments Abbott has provided and reimbursement received from CMS for the MC Device and TMVR procedure performed on Medicare patients).[24]

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[23] Abbott's payments to physicians include general payments, such as speaker honorarium, consulting fees and meals, and associated research funding payments, including, for example, Abbott's payments to the COAPT trial investigators.

[24] The estimated reimbursement amount is based on available CMS data from 2015–17 for TMVR procedures performed by the physicians referenced here. Based on Abbott's data

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- Dr. T.B. – Interventional cardiologist at Abrazo Arizona Heart Hospital, Phoenix, AZ.

  Abbott payments: $47,000.00

  CMS reimbursement: $4.3 million
- Dr. B.C. – Interventional cardiologist at Ascension Via Christi Hospital in Wichita, KS.

  Abbott payments: $766,000.00

  CMS reimbursement: $4.3 million
- Dr. H.N. – Chief of cardiology at Dignity St. Joseph's Hospital in Phoenix, AZ, and one of Relator's target implanting physicians.

  Abbott payments: $73,000.00

  CMS reimbursement: $1 million
- Dr. M.P. – Interventional cardiologist at Scripps Hospital in La Jolla, CA, and one of Relator's targeted implanting physicians.

  Abbott payments: $470,000.00

  CMS reimbursement: $3 million
- Dr. M.R. – Interventional cardiologist at NorthShore University Health System in Evanston, IL.

  Abbott payments: $520,000.00

  CMS reimbursement: $2 million
- Dr. M.R. – Cardiologist at Sanger Heart and Vascular Institute, Atrium Health in Charlotte, NC.

  Abbott payments: $300,000.00

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regarding the increase in the number of TMVR procedures performed since 2017, these amounts have likely increased significantly over the past three years. Abbott's payments are based on available CMS Open Payments data from 2013-2019.

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CMS reimbursement: $4 million

- Dr. J.R. – Interventional cardiologist at U.C. Davis Medical Centre in Sacramento, CA.

  Abbott payments: $400,000.00

  CMS reimbursement: $3 million

- Dr. P.S. – Interventional cardiologist at Minneapolis Heart Institute at Abbott Northwest Hospital in Minneapolis, MN.

  Abbott payments: $942,000.00
  CMS reimbursement: $2 million

202. Abbott is clearly aware that it is improper to engage in practice-building and patient referral activities as an inducement for physicians to use the MC Device. Despite this knowledge, or perhaps because of it, Abbott has attempted to guide its sales and marketing staff about how to conceal the true purpose of its schemes by having its management instruct all employees that "Abbott must not engage in activities aimed ***solely*** to help a MitraClip implanting site (customer) build their practice by directing or encouraging referring physicians to send their potential MitraClip candidates to a specific implanting site for treatment." (Abbott 2Q16 Structural Heart Quota and Compensation Rollout: Therapy Development Specialist, Pages 7 and 11.)

203. At all pertinent times, Abbott has engaged in its practice building activities based upon unlawful inducements throughout the United States on a pervasive basis and in a continuous manner.

204. Abbott's attempt to conceal the nature of its kickback schemes through this instruction is plainly misguided because an activity violates the AKS if ***one purpose*** of the related remuneration is to induce a person to use a service or product for which payment is made under a government funded healthcare program, not, as Abbott instructed its sales staff, if it is the remuneration's sole purpose.

iii. Abbott Disguises Kickback Schemes

205. Lavish meals, private dinners, and other forms of illegal remuneration form the basis of Abbott's partnerships with referring and implanting physicians and hospitals. However, given the fraudulent nature of these arrangements, Abbott management has cultivated a sales team culture in which sales representatives are encouraged to hide excess spending (in violation of Abbott's own established spend limit guidelines) and to disguise social gatherings as "educational" programs.

206. For example, Meadors asked Relator to organize the first TMVR Summit in January 2017. Relator was instructed by Meadors to secure a specific venue for the event, a five-star luxury resort, and was instructed to characterize any of the costs exceeding the $125.00 per person limit as a "room charge," as that would not be included in the per person spend calculation and, thus, would not have to be reported by Abbott to CMS. This event was a great success for Abbott, but because the final bill was well over Abbott's per person spend limit, Relator was directed by Meadors to obtain assistance from his/her colleague, Megan Oh, who had experience with organizing these events and with hiding event excessive spend charges (and who would later be promoted to Senior Project Manager as discussed in Part B.1. *supra*).

207. When Relator showed Oh the event invoices in an email on January 18, 2017, however, Oh told Relator that the number was so high, the overspending so egregious, that, despite Ms. Megan Oh's experience with hiding excessive charges for these lavish events, she did not have a viable solution to hide it. In fact, she said that the per person cost – which she confirmed to be $267.63, including the cost of drinks and sushi – was "the highest [she has] ever seen with any hotel." Ultimately, Meadors told Relator to use his/her Abbott credit card to pay the outstanding balance so the payment would not be associated with the event and, thus, would not have to be reported by the Company.

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208. Meadors was aware that this advice was contrary to Abbott's own "The Sunshine Act" information manual and the guidance given in Abbott's "Policies and Practices" Training Guidelines, which explicitly state that *all* meal spend must be reported accurately. In fact, when Relator reported this example of Abbott's exceeding the per person spend violation to Abbott's Office of Ethics and Compliance, he/she was informed that Meadors used to be in charge of Abbott's Marketing Department and, thus, should have known both that this method of payment was inappropriate and also that this event should have been executed by the Marketing Department instead of the Sales Department. Despite the fact that Relator informed Abbott's Office of Ethics and Compliance about this incident, no remedial action was taken and, instead, Abbott acted as if the fraud had arisen as a result of a "misunderstanding," and still misreported to the government the cost of the meals for each attendee.

209. In addition, if the final bill for an event exceeded the per person spend limit, it was a common practice at Abbott for the sales representatives – with their managers' knowledge and consent – to add to the attendee list of an event the names of people who did not attend. Some of Relator's colleagues who engaged in this practice were John Rupp, Rafid Haddad, Nate Foreman, Wes Baldwin, Dan Meeker, Milos Balsic, and Mike Quinn.

210. Relator was also instructed on occasion to arrange "dine and dash" programs. The AdvaMed Code of Ethics specifically clarifies that "[a] Company may not provide a meal or refreshments . . . if a Company representative is not present (such as a "dine & dash" program)." Despite this clear guidance, Abbott representatives are told to schedule dinners and events anyway because Abbott will "pick up the bill." For example, Relator arranged a lunch event for Dr. H.N. on March 8, 2016 with catering from Blu Sushi that amounted to $433.71 in food. When he/she spoke to Mike Quinn beforehand, however, he informed him/her that "[he/she] can cater it, they just don't want us [Abbott] in the

actual meeting." Instead, Relator only dropped the food off and was not present for the "presentation."

211. Also problematic at Abbott promotional speaker programs, including the TMVR Summit, is its management's decision to allow speakers to create their own slide decks for speaker programs performed at the event. Although Meadors offered input to each speaker about the content for his/her presentations for the TMVR Summit, the slide decks that each speaker created and used for the event did not go through Abbott's formal vetting process and, thus, were not guaranteed to be of significant education value nor assigned an approval number. When Relator needed to get the speaker payment checks approved, however, he/she was instructed by management in a February 15, 2017 email to simply use a phony Accounts Payable ("AP") number for the slide decks so the speakers could get paid. This practice was exemplified by Dr. R.G.'s previously mentioned "presentation" that included only a few, non-educational, and non-substantive slides that he prepared himself. Despite this, Dr. R.G. was still paid $2,500 even though his slide deck was marked with a phony AP number.

212. Relator was routinely instructed to send a simple message to referring physicians, if you see MR in your patient, "just send it" – that is, physicians should just send every MR case to implanting physicians for treatment as opposed to trying to distinguish between forms of MR or considering other treatment options, because "everything can be clipped." In fact, in response to a surgeon who had to remove a failed MC Device from a patient and commented, "Are we clipping too many patients?" an implanting physician responded that he did not disagree and that "we get pressure for being "low volume" due to following the actual CMS guidelines of DMR AND inoperable."

213. Indeed, Abbott regularly requires its sales and marketing employees to partner closely with physicians to promote the MC Device, even at the expense of the patient's

health. For example, Abbott AMs and CESs are required to work closely with the physicians in the catheter lab during the TMVR procedure. Relator has heard two of his/her colleagues, Michael Quinn and Rafid Haddad, bragging about how proud they are of instructing their implanting physicians to "beta block the s#@t out of patients" who experience dangerously elevated valve gradient levels during the MC Device procedure, all to ensure that the MC Device is widely used. Relator was also present at a meeting in March 2016 with Mr. Haddad and Dr. Y.L., who had requested information about how to surgically remove the MC Device from one of his patients who was experiencing severe health issues related to the device. Instead of providing information in response to Dr. Y.L.'s request directly, Mr. Haddad, who is not a doctor, provided patient management advice and told Dr. Y.L. to leave the device intact and beta block his patient – an instruction that implicates grave patient issues and was directly contrary to the doctor's own recommendations.

214. Additionally, Meadors arranged for one of the paid speakers at the TMVR Summit, Dr. G.T., to attend an "off-label" procedure performed earlier that day where a MC Device was used in the tricuspid valve to treat tricuspid regurgitation ("TR"). That evening at the TMVR Summit, Dr. G.T. addressed more than 100 cardiologists and surgeons and discussed the "off-label" procedure he had seen earlier in the day; he told the attendees how he had just observed a case that day and assured them that this was the future of cardiac procedures. Meadors created the path for this off-label discussion by arranging for the speaker to observe the procedure and then present his observations to the attendees at the evening's event.[25] Meadors allowed and encouraged this off-label speaking engagement in an effort to assist the TMVR Summit speaker panel in building their practices by attracting new MC Device procedure referral business.

[25] According to Relator, Meadors often spoke about other off-label opportunities in "code" to disguise the scheme.

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COUNT I- FEDERAL FALSE CLAIMS ACT
31 U.S.C. §§ 3729(a)(1)(A)

215. Relator repeats and re-alleges each and every allegation contained in the paragraphs above as though fully set forth herein.

216. This claim is a claim by Relator, on behalf of the United States, for treble damages and penalties under the FCA, 31 U.S.C. §§ 3729-3733, against Defendants, for knowingly causing to be presented false claims to Government Healthcare Programs.

217. Defendants have caused physicians and hospitals to submit claims forms for payment, knowing that such false claims would be submitted to the federal and state Government Healthcare Programs for reimbursement, and knowing that such Government Healthcare Programs were unaware that they were reimbursing for the TMVR procedure, including the cost of Defendants' MC Device, induced by kickbacks in the form of illegal remuneration through patient referrals, cash speaking honoraria payments, and free patient marketing services, and, therefore, false claims.

218. By virtue of the acts alleged herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the United States Government for reimbursement to healthcare providers in the millions of dollars, in violation of the FCA, 31 U.S.C. § 3729, *et seq*. and the AKS, 42 U.S.C. § 1320a-7b(b)(2)(A).

COUNT II- FEDERAL FALSE CLAIMS ACT
31 U.S.C. §§ 3729(a)(1)(B)

219. Relator repeats and re-alleges each and every allegation contained in the paragraphs above and though fully set forth herein.

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220. This claim is a claim by Relator, on behalf of the United States, for treble damages and penalties under the FCA, 31 U.S.C. §§ 3729-3733, against Defendants, for knowingly causing to be presented false claims to Government Healthcare Programs.

221. Defendants knowingly made, used, or caused to be made or used, false records or statements material to false or fraudulent claims to the United States through concealment of Defendants' illegal remuneration schemes.

222. By virtue of the acts alleged herein, Defendants knowingly used, or caused to be used, false records or statements, and the United States has suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT III- FEDERAL FALSE CLAIMS ACT

31 U.S.C. §§ 3729(a)(1)(C)

223. Relators repeats and re-alleges each and every allegation contained in the paragraphs above as though fully set forth herein.

224. Defendants knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money to the United States in violation of 31 U.S.C. §3729(a)(1)(G) and/or conspired to commit such acts or omissions in violation of 31 U.S.C. §3729(a)(1)(C).

COUNT IV- CALIFORNIA FALSE CLAIMS ACT

Cal. Gov't. Code § 12650, *et seq.*

225. Relator repeats and re-alleges each and every allegation contained in the paragraphs above as though fully set forth herein.

226. This is a *qui tam* action brought by Relator on behalf of the State of California to recover treble damages and civil penalties under the California False Claims Act, Cal. Gov't. Code § 12650, *et seq.*

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227. Defendants violated Cal. Bus. & Prof. Code § 650 and 650.1 and Cal. Welf. & Inst. Code §14107.2 by engaging in the conduct alleged herein.

228. Defendants furthermore violated Cal. Gov't Code § 12651(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of California by their deliberate and systematic violation of federal and state laws, including the FCA, federal AKS, Cal. Bus. & Prof. Code § 650-650.1 and Cal. Welf. & Inst. Code § 14107.2 and by virtue of the fact that none of the claims submitted in connection with their conduct were eligible for reimbursement by the Government Healthcare Programs.

229. The State of California, by and through the California Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

230. Compliance with applicable Medicare, Medi-Cal, and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of California in connection with Defendants' conduct. Compliance with applicable California statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of California.

231. Had the State of California known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.

232. As a result of Defendants' violations of Cal. Gov't Code § 12651(a), the State of California has been damaged in an amount far in excess of millions of dollars, exclusive of interest.

233. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Cal. Gov't Code § 12652(c) on behalf of itself and the State of California.

234. Relator requests this Court to accept supplemental jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of California in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF CALIFORNIA:

(1) Three times the amount of actual damages which the State of California has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $5,500 and up to $11,000 for each false claim which Defendants presented or caused to be presented to the State of California;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATOR:

(1) The maximum amount allowed pursuant to Cal. Gov't Code § 12652 and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

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COUNT V- COLORADO MEDICAID FALSE CLAIMS ACT

(C.R.S.A. § 25.5-4-304, *et seq.*)

235. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

236. This is a *qui tam* action brought by Relator on behalf of the State of Colorado to recover treble damages and civil penalties under the Colorado Medicaid False Claims Act, C.R.S.A. § 25.5-4-304, *et seq.*

237. Defendants violated the Colorado Medicaid False Claims Act by engaging in the conduct alleged herein.

238. Defendants further violated the Colorado Medicaid False Claims Act and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Colorado by their deliberate and systematic violation of federal and state laws, including the FCA, federal AKS and C.R.S.A. § 24-31-809, and by virtue of the fact that none of the claims submitted in connection with their conduct were eligible for reimbursement by the Government Healthcare Programs.

239. The State of Colorado, by and through the Colorado Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

240. Compliance with applicable Medicare, Medicaid, and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the State of Colorado in connection with Defendants' conduct. Compliance with applicable Colorado statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Colorado.

241. Had the State of Colorado known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with

Defendants' conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.

242. As a result of Defendants' violations of the Colorado Medicaid False Claims Act, the State of Colorado has been damaged in an amount far in excess of millions of dollars, exclusive of interest.

243. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint and has brought this action pursuant to the Colorado Medicaid False Claims Act on behalf of itself and the State of Colorado.

244. Relator requests this Court to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of Colorado, in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF COLORADO:

(1) Three times the amount of actual damages which the State of Colorado has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $12,537 and not more than $25,0761, for each false claim which Defendants caused to be presented to the State of Colorado;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATOR:

(1) The maximum amount allowed pursuant to Colorado Medicaid False Claims Act and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in

connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT VI – CONNECTICUT FALSE CLAIMS ACT

(Conn. Gen. Stat. § 4-274, *et seq.*)

245. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

246. This is a *qui tam* action brought by Relator on behalf of the State of Connecticut to recover treble damages and civil penalties under the Connecticut False Claims Act, Conn. Gen. Stat. § 4-274, *et seq*.

247. Defendants violated the Connecticut False Claims Act, Conn. Gen. Stat. § 4-274, *et seq*., by engaging in the conduct alleged herein.

248. Defendants further violated the Connecticut False Claims Act and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Connecticut by their deliberate and systematic violation of federal and state laws, including the FCA, federal AKS, and Conn. Gen. Stat. § 53a-161c, and by virtue of the fact that none of the claims submitted in connection with their conduct were eligible for reimbursement by the Government Healthcare Programs.

249. The State of Connecticut, by and through the Connecticut Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

250. Compliance with applicable Medicare, Medicaid, and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the State of Connecticut in connection with Defendants' conduct. Compliance with applicable Connecticut statutes,

regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Connecticut.

251. Had the State of Connecticut known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.

252. As a result of Defendants' violations of the Connecticut False Claims Act, the State of Connecticut has been damaged in an amount far in excess of millions of dollars, exclusive of interest.

253. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint and has brought this action pursuant to the Connecticut False Claims Act on behalf of itself and the State of Connecticut.

254. Relator requests this Court to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of Connecticut, in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF CONNECTICUT:

(1) Three times the amount of actual damages which the State of Connecticut has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of Connecticut;

(3) Prejudgment interest; and

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(4) All costs incurred in bringing this action.

To RELATOR:

(1) The maximum amount allowed pursuant to Connecticut False Claims Act, Conn. Gen. Stat. § 4-274, *et seq*., and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Plaintiffs-Relators incurred in connection with this action;

(2) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT VII – DELAWARE FALSE CLAIMS AND REPORTING ACT

(Title 6, Chapter 12, Delaware Code)

255. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

256. This is a *qui tam* action brought by Relator on behalf of the State of Delaware to recover treble damages and civil penalties under the Delaware False Claims and Reporting Act, Title 6, Chapter 12 of the Delaware Code.

257. Defendants violated 31 Del. C. § 1005 by engaging in the conduct alleged herein.

258. Defendants further violated 6 Del. C. § 1201(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Delaware by their deliberate and systematic violation of federal and state laws, including the FCA, the AKS, and 31 Del. C. § 1005, and by virtue of the fact that none of the claims submitted in connection with their conduct were eligible for reimbursement by the Government Healthcare Programs.

259. The State of Delaware, by and through the Delaware Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

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260. Compliance with applicable Medicare, Medicaid, and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the State of Delaware in connection with Defendants' conduct. Compliance with applicable Delaware statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Delaware.

261. Had the State of Delaware known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.

262. As a result of Defendants' violations of 6 Del. C. § 1201(a), the State of Delaware has been damaged in an amount far in excess of millions of dollars, exclusive of interest.

263. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint and has brought this action pursuant to 6 Del. C. § 1203(b) on behalf of itself and the State of Delaware.

264. Relator requests this Court to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of Delaware, in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendant:

To the STATE OF DELAWARE:

(1) Three times the amount of actual damages which the State of Delaware has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $10,957 and not more than $21,916 for each false claim which Defendants caused to be presented to the State of Delaware;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATOR:

(1) The maximum amount allowed pursuant to 6 Del C. § 1205, and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT VIII – FLORIDA FALSE CLAIMS ACT

(Fla. Stat. § 68.081, *et seq.*)

265. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

266. This is a *qui tam* action brought by Relator on behalf of the State of Florida to recover treble damages and civil penalties under the Florida False Claims Act, Fla. Stat. § 68.082, *et seq*.

267. Defendants violated Fla. Stat. § 409.920(2) (3) and (5) and §456.054(2) by engaging in the conduct alleged herein.

268. Defendants further violated Fla. Stat. § 68.082(2) and knowingly caused hundreds of thousands of false claims to be made, used, and presented to the State of Florida by their deliberate and systematic violation of federal and state laws, including the FCA, federal AKS, Fla. Stat. § 409.920(2)(a) (3) and (5) and §456.054(2), and by

virtue of the fact that none of the claims submitted in connection with their conduct were eligible for reimbursement by the Government Healthcare Programs.

269. The State of Florida, by and through the Florida Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

270. Compliance with applicable Medicare, Medicaid, and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the State of Florida in connection with Defendants' conduct. Compliance with applicable Florida statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Florida.

271. Had the State of Florida known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.

272. As a result of Defendants' violations of Fla. Stat. § 68.082(2), the State of Florida has been damaged in an amount far in excess of millions of dollars, exclusive of interest.

273. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint and has brought this action pursuant to Fla. Stat. § 68.083(2) on behalf of itself and the State of Florida.

274. Relator requests this Court to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of Florida, in the operation of its Medicaid program.

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WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendant:

To the STATE OF FLORIDA:

(1) Three times the amount of actual damages which the State of Florida has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of Florida;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATOR:

(1) The maximum amount allowed pursuant to Fla. Stat. § 68.085 and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT IX – GEORGIA FALSE MEDICAID CLAIMS ACT

(Ga. Code Ann., § 49-4-168, *et seq*).

275. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

276. This is a *qui tam* action brought by Relator on behalf of the State of Georgia to recover treble damages and civil penalties under the Georgia False Medicaid Claims Act, Ga. Code Ann., § 49-4-168, *et seq.*

277. Defendants violated the Georgia False Medicaid Claims Act, Ga. Code Ann., § 49-4-168, *et seq.*, by engaging in the conduct alleged herein.

278. Defendants further violated the Georgia False Medicaid Claims Act and knowingly caused hundreds of thousands of false claims to be made, used and presented

to the State of Georgia by their deliberate and systematic violation of federal and state laws, including the FCA and the federal AKS, and by virtue of the fact that none of the claims submitted in connection with their conduct were eligible for reimbursement by the Government Healthcare Programs.

279. The State of Georgia, by and through the Georgia Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

280. Compliance with applicable Medicare, Medicaid, and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of Georgia in connection with Defendants' conduct. Compliance with applicable Georgia statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Georgia.

281. Had the State of Georgia known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.

282. As a result of Defendants' violations of the Georgia False Medicaid Claims Act, the State of Georgia has been damaged in an amount far in excess of millions of dollars, exclusive of interest.

283. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint and has brought this action pursuant to the Georgia False Medicaid Claims Act on behalf of itself and the State of Georgia.

284. Relator requests this Court to accept supplemental jurisdiction of this related

state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of Georgia, in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF GEORGIA:

(1) Three times the amount of actual damages which the State of Georgia has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $12,537 and not more than $25,076 for each false claim which Defendants caused to be presented to the State of Georgia;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATOR:

(1) The maximum amount allowed pursuant to Georgia False Medicaid Claims Act, Ga. Code Ann., § 49-4-168, and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT X – HAWAII FALSE CLAIMS ACT

(Haw. Rev. Stat. § 661-21, *et seq.*)

285. Relator repeats and realleges each and every allegation contained in the paragraphs above as if fully set forth herein.

286. This is a *qui tam* action brought by Relator on behalf of the State of Hawaii to recover treble damages and civil penalties under the Hawaii False Claims Act, Haw. Rev. Stat. § 661-21, *et seq.*

287. Defendants violated Haw. Rev. Stat. §661-21(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Hawaii by its deliberate and systematic violation of federal and state laws, including the FCA and AKS, and by virtue of the fact that none of the claims submitted in connection with its conduct were eligible for reimbursement by the Government Healthcare Programs.

288. The State of Hawaii, by and through the Hawaii Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

289. Compliance with applicable Medicare, Medicaid, and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of Hawaii in connection with Defendants' conduct. Compliance with applicable Hawaii statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Hawaii.

290. Had the State of Hawaii known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.

291. As a result of Defendants' violations of Haw. Rev. Stat. § 661-21(a), the State of Hawaii has been damaged in an amount far in excess of millions of dollars, exclusive of interest.

292. Relator is a private citizen with direct and independent knowledge of the

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allegations of this Complaint and has brought this action pursuant to Haw. Rev. Stat. § 661-25(a) on behalf of itself and the State of Hawaii.

293. Relator requests this Court to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of Hawaii, in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF HAWAII:

(1) Three times the amount of actual damages which the State of Hawaii has sustained as a result of Defendants' illegal conduct;

(2) A civil penalty of not less than $11,463 and not more than $22,927 for each false claim which Defendants caused to be presented to the State of Hawaii;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATOR:

(1) The maximum amount allowed pursuant to Haw. Rev. Stat. §661-27 and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT XI – ILLINOIS FALSE CLAIMS ACT

(740 ILCS 175, *et seq.*)

294. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

295. This is a *qui tam* action brought by Relator on behalf of the State of Illinois to recover treble damages and civil penalties under the Illinois False Claims Act, 740 ILCS 175, *et seq.*

296. Defendants violated 305 ILCS 5/8A-3(b) by engaging in the conduct alleged herein.

297. Defendants furthermore violated 740 ILCS 175/3(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Illinois by their deliberate and systematic violation of federal and state laws, including the FCA, federal AKS, and the Illinois Vendor Fraud and Kickback statute, and by virtue of the fact that none of the claims submitted in connection with their conduct were eligible for reimbursement by the Government Healthcare Programs.

298. The State of Illinois, by and through the Illinois Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

299. Compliance with applicable Medicare, Medicaid, and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the State of Illinois in connection with Defendants' conduct. Compliance with applicable Illinois statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Illinois.

300. Had the State of Illinois known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.

301. As a result of Defendants' violations of 740 ILCS 175/3(a), the State of Illinois has been damaged in an amount far in excess of millions of dollars, exclusive of interest.

302. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint and has brought this action pursuant to 740 ILCS 175/3(b) on behalf of itself and the State of Illinois.

303. Relator requests this Court to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of Illinois, in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF ILLINOIS:

(1) Three times the amount of actual damages which the State of Illinois has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $12,537 and not more than $25,076 for each false claim which Defendants caused to be presented to the State of Illinois;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATOR:

(1) The maximum amount allowed pursuant to 740 ILCS 175/4(d) and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

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COUNT XII – INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT

(Indiana Code 5-11-5.5, *et seq.*)

304. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

305. This is a *qui tam* action brought by Relator on behalf of the State of Indiana to recover treble damages and civil penalties under the Indiana False Claims and Whistleblower Protection Act, Indiana Code 5-11-5.5, *et seq.*

306. Defendants violated Indiana's False Claims Act by engaging in the conduct alleged herein.

307. Defendants further violated Indiana's False Claims Act and knowingly caused hundreds of thousands of false claims to be made, used, and presented to the State of Indiana by their deliberate and systematic violation of federal and state laws, including the FCA and federal AKS, and by virtue of the fact that none of the claims submitted in connection with their conduct were eligible for reimbursement by the Government Healthcare Programs.

308. The State of Indiana, by and through the Indiana Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

309. Compliance with applicable Medicare, Medicaid, and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the State of Indiana in connection with Defendants' conduct. Compliance with applicable Indiana statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Indiana.

310. Had the State of Indiana known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with

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Defendants' conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.

311. As a result of Defendants' violations of Indiana's False Claims Act, the State of Indiana has been damaged in an amount far in excess of millions of dollars, exclusive of interest.

312. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint and has brought this action pursuant to Indiana Code § 5-11-5.5, *et seq.,* on behalf of itself and the State of Indiana.

313. Relator requests this Court to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of Indiana, in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF INDIANA:

(1) Three times the amount of actual damages which the State of Indiana has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $5,000 for each false claim which Defendants caused to be presented to the State of Indiana;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATOR:

(1) The maximum amount allowed pursuant to Indiana Code § 5-11-5.5, *et seq.,* and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT XIII - IOWA FALSE CLAIMS ACT

(I.C.A. § 685.1, *et seq.*)

314. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

315. This is a *qui tam* action brought by Relator on behalf of the State of Iowa to recover treble damages and civil penalties under the Iowa False Claims Act, I.C.A. § 685.1, *et seq*.

316. Defendants violated the Iowa False Claims Act, I.C.A. § 685.1, *et seq*., by engaging in the conduct described herein.

317. Defendants furthermore violated the Iowa False Claims Act, I.C.A. § 685.1, *et seq*., and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Iowa by their deliberate and systematic violation of federal and state laws, including the FCA, federal AKS, and by virtue of the fact that none of the claims submitted in connection with their conduct were eligible for reimbursement by the Government Healthcare Programs.

318. The State of Iowa, by and through the Iowa Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

319. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the State of Iowa in connection with Defendants' conduct. Compliance with applicable Iowa statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Iowa.

320. Had the State of Iowa known that Defendants were violating the federal and

state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.

321. As a result of Defendants' violations of the Iowa False Claims Act, I.C.A. § 685.1, *et seq*., the State of Iowa has been damaged in an amount far in excess of millions of dollars, exclusive of interest.

322. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint and has brought this action pursuant to Iowa False Claims Act, I.C.A. § 685.1, *et seq*., on behalf of itself and the State of Iowa.

323. Relator requests this Court to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of Iowa, in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF IOWA:

(1) Three times the amount of actual damages which the State of Iowa has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $12,537 and not more than $25,076 for each false claim which Defendants caused to be presented to the State of Iowa;

(3) Prejudgment interest; and/or

(4) All costs incurred in bringing this action.

To RELATOR:

(1) The maximum amount allowed pursuant to Iowa False Claims Act, I.C.A. § 685.1, *et seq*., and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT XIV – LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW

(La. Rev. Stat. Ann. § 46:437.1, *et seq.*)

324. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

325. This is a *qui tam* action brought by Relator on behalf of the State of Louisiana to recover treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 46:437.1, *et seq.*

326. Defendants violated La. Rev. Stat. Ann. § 46:438.2(A) by engaging in the conduct alleged herein.

327. Defendants further violated La. Rev. Stat. Ann. § 46:438.3 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Louisiana by their deliberate and systematic violation of federal and state laws, including the FCA, federal AKS and La. Rev. Stat. Ann. § 46:438.2(A), and by virtue of the fact that none of the claims submitted in connection with their conduct were eligible for reimbursement by the Government Healthcare Programs.

328. The State of Louisiana, by and through the Louisiana Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

329. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the State of Louisiana in connection with Defendants' conduct. Compliance with applicable Louisiana statutes, regulations

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and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Louisiana.

330. Had the State of Louisiana known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.

331. As a result of Defendants' violations of La. Rev. Stat. Ann. § 46:438.3, the State of Louisiana has been damaged in an amount far in excess of millions of dollars, exclusive of interest.

332. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint and has brought this action pursuant to La. Rev. Stat. Ann. §46:439.1(A) on behalf of itself and the State of Louisiana.

333. Relator requests this Court to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of Louisiana, in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF LOUISIANA:

(1) Three times the amount of actual damages which the State of Louisiana has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of Louisiana;

(3) Prejudgment interest; and

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(4) All costs incurred in bringing this action.

To RELATOR:

(1) The maximum amount allowed pursuant to La. Rev. Stat. § 46:439.4(A) and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT XV – MICHIGAN MEDICAID FALSE CLAIMS ACT

(Mich. Comp. Laws Ann. § 400.603, *et seq.*)

334. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

335. This is a *qui tam* action brought by Relator on behalf of the State of Michigan to recover treble damages and civil penalties under Michigan's Medicaid False Claims Act, Mich. Comp. Laws Ann. § 400.603, *et seq.*

336. Defendants violated the Michigan Medicaid False Claims Act by engaging in the conduct alleged herein.

337. Defendants further violated Michigan law and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Michigan by their deliberate and systematic violation of federal and state laws, including the FCA and federal AKS, and by virtue of the fact that none of the claims submitted in connection with their conduct were eligible for reimbursement by the Government Healthcare Programs.

338. The State of Michigan, by and through the Michigan Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

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339. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the State of Michigan in connection with Defendants' conduct. Compliance with applicable Michigan statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Michigan.

340. Had the State of Michigan known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.

341. As a result of Defendants' violations of the Michigan Medicaid False Claims Act, the State of Michigan has been damaged in an amount far in excess of millions of dollars, exclusive of interest.

342. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint and has brought this action pursuant to the Michigan Medicaid False Claims Act on behalf of itself and the State of Michigan.

343. Relator requests this Court to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of Michigan, in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF MICHIGAN:

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(1) Three times the amount of actual damages which the State of Michigan has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Michigan;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATOR:

(1) The maximum amount allowed pursuant to the Medicaid False Claims Act and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT XVI – MINNESOTA FALSE CLAIMS ACT

(M.S.A. § 15C.01, *et seq.*)

344. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

345. This is a *qui tam* action brought by Relator on behalf of the State of Minnesota to recover treble damages and civil penalties under the Minnesota False Claims Act, M.S.A. § 15C.01, *et seq.*

346. Defendants violated the Minnesota False Claims Act by engaging in the conduct alleged herein.

347. Defendants further violated the Minnesota False Claims Act and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Minnesota by their deliberate and systematic violation of federal and state laws, including the FCA, federal AKS and M.S.A. § 256B.0914, and by virtue of the fact that none of the claims submitted in connection with their conduct were eligible for

reimbursement by the Government Healthcare Programs.

348. The State of Minnesota, by and through the Minnesota Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

349. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the State of Minnesota in connection with Defendants' conduct. Compliance with applicable Minnesota statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Minnesota.

350. Had the State of Minnesota known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.

351. As a result of Defendants' violations of the Minnesota False Claims Act, the State of Minnesota has been damaged in an amount far in excess of millions of dollars, exclusive of interest.

352. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint and has brought this action pursuant to the Minnesota False Claims Act, on behalf of itself and the State of Minnesota.

353. Relator requests this Court to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of Minnesota, in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF MINNESOTA:

(1) Three times the amount of actual damages which the State of Minnesota has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of Minnesota;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATOR:

(1) The maximum amount allowed pursuant to the Minnesota False Claims Act and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT XVII – MONTANA FALSE CLAIMS ACT

(MCA § 17-8-401, *et seq.*)

354. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

355. This is a *qui tam* action brought by Relator on behalf of the State of Montana to recover treble damages and civil penalties under the Montana False Claims Act, MCA § 17-8-401, *et seq.*

356. Defendants violated the Montana False Claims Act by engaging in the conduct alleged herein.

357. Defendants furthermore violated the Montana False Claims Act and knowingly caused hundreds of thousands of false claims to be made, used and presented

to the State of Montana by their deliberate and systematic violation of federal and state laws, including the FCA, federal AKS and MCA § 45-6-313, and by virtue of the fact that none of the claims submitted in connection with their conduct were eligible for reimbursement by the Government Healthcare Programs.

358. The State of Montana, by and through the Montana Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

359. Compliance with applicable Medicare, Medicaid, and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the State of Montana in connection with Defendants' conduct. Compliance with applicable Montana statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Montana.

360. Had the State of Montana known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.

361. As a result of Defendants' violations of the Montana False Claims Act, the State of Montana has been damaged in an amount far in excess of millions of dollars, exclusive of interest.

362. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint and has brought this action pursuant to the Montana False Claims Act, on behalf of themselves and the State of Montana.

363. Relator requests this Court to accept supplemental jurisdiction of this related

state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of Montana, in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF MONTANA:

(1) Three times the amount of actual damages which the State of Montana has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of Montana;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATOR:

(1) The maximum amount allowed pursuant to Montana False Claims Act and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT XVIII – NEVADA FALSE CLAIMS ACT

(N.R.S. § 357.010, *et seq.*)

364. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

365. This is a *qui tam* action brought by Relator on behalf of the State of Nevada to recover treble damages and civil penalties under the Nevada False Claims Act, N.R.S. § 357.010, *et seq.*

366. Defendants violated N.R.S. § 422.560 by engaging in the conduct alleged herein.

367. Defendants further violated N.R.S. § 357.040(1) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Nevada by their deliberate and systematic violation of federal and state laws, including the FCA, federal AKS and N.R.S. § 422.560, and by virtue of the fact that none of the claims submitted in connection with their conduct were eligible for reimbursement by the Government Healthcare Programs.

368. The State of Nevada, by and through the Nevada Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

369. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the State of Nevada in connection with Defendants' conduct. Compliance with applicable Nevada statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Nevada.

370. Had the State of Nevada known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.

371. As a result of Defendants' violations of N.R.S. § 357.040(1), the State of Nevada has been damaged in an amount far in excess of millions of dollars, exclusive of interest.

372. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint and has brought this action pursuant to N.R.S. § 357.080(1), on behalf of themselves and the State of Nevada.

373. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Nevada in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the STATE OF NEVADA:

(1) Three times the amount of actual damages which the State of Nevada has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $12,537 and not more than $25,076 for each false claim which Defendants caused to be presented to the State of Nevada;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATOR:

(1) The maximum amount allowed pursuant to N.R.S. § 357.210 and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT XIX – NEW JERSEY FALSE CLAIMS ACT

(N.J.S.A. § 2A:32C-1, *et seq.*)

374. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

375. This is a *qui tam* action brought by Relator on behalf of the State of New

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Jersey to recover treble damages and civil penalties under the New Jersey False Claims Act, N.J.S.A. § 2A:32C-1, *et seq*.

376. Defendants violated the New Jersey False Claims Act by engaging in the conduct alleged herein.

377. Defendants further violated the New Jersey False Claims Act and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of New Jersey by their deliberate and systematic violation of federal and state laws, including the FCA, federal AKS and N.J.S.A. § 30:4D-17, and by virtue of the fact that none of the claims submitted in connection with their conduct were eligible for reimbursement by the Government Healthcare Programs.

378. The State of New Jersey, by and through the New Jersey Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

379. Compliance with applicable Medicare, Medicaid, and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the State of New Jersey in connection with Defendants' conduct. Compliance with applicable New Jersey statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of New Jersey.

380. Had the State of New Jersey known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.

381. As a result of Defendants' violations of the New Jersey False Claims Act, the

State of New Jersey has been damaged in an amount far in excess of millions of dollars, exclusive of interest.

382. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to the New Jersey False Claims Act, on behalf of itself and the State of New Jersey.

383. Relator requests this Court to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of New Jersey, in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF NEW JERSEY:

(1) Three times the amount of actual damages which the State of New Jersey has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $12,537 and not more than $25,076 for each false claim which Defendants caused to be presented to the State of New Jersey;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATOR:

(1) The maximum amount allowed pursuant to New Jersey False Claims Act and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Plaintiffs-Relators incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

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COUNT XX – NEW MEXICO MEDICAID FALSE CLAIMS ACT

(N.M. Stat. Ann. §§ 27-14-1, *et seq.*)

384. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

385. This is a *qui tam* action brought by Relator on behalf of the State of New Mexico to recover treble damages and civil penalties under the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §§ 27-14-1, *et seq*.

386. Defendants violated N.M. Stat. Ann. § 30-44-7, *et seq*., by engaging in the conduct alleged herein.

387. Defendants further violated N.M. Stat. Ann. §§ 27-14-1, *et seq*., and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of New Mexico by their deliberate and systematic violation of federal and state laws, including the FCA and federal AKS, and by virtue of the fact that none of the claims submitted in connection with their conduct were eligible for reimbursement by the Government Healthcare Programs.

388. The State of New Mexico, by and through the New Mexico Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

389. Compliance with applicable Medicare, Medicaid, and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the State of New Mexico in connection with Defendants' conduct. Compliance with applicable New Mexico statutes, regulations, and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of New Mexico.

390. Had the State of New Mexico known that Defendants were violating the

federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.

391. As a result of Defendants' violations of N.M. Stat. Ann. §§ 27-14-1, *et seq.*, the State of New Mexico has been damaged in an amount far in excess of millions of dollars, exclusive of interest.

392. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint and has brought this action pursuant to N.M. Stat. Ann. §§ 27-14-1, *et seq.*, on behalf of itself and the State of New Mexico.

393. Relator requests this Court to accept supplemental jurisdiction of this related state claim, as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of New Mexico, in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF NEW MEXICO:

(1) Three times the amount of actual damages which the State of New Mexico has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of New Mexico;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATOR:

(1) The maximum amount allowed pursuant to N.M. Stat. Ann. §§ 27-14-1, *et seq.*, and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT XXI – NEW YORK FALSE CLAIMS ACT

(State Finance Law § 189)

394. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

395. This is a *qui tam* action brought by Relator on behalf of the State of New York to recover treble damages and civil penalties under the New York State False Claims Act, State Finance Law § 189.

396. Defendants violated New York law by engaging in the conduct alleged herein.

397. Defendants further violated the New York State False Claims Act, and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of New York, by their deliberate and systematic violation of federal and state laws, including the FCA and federal AKS, and by virtue of the fact that none of the claims submitted in connection with their conduct were eligible for reimbursement by the Government Healthcare Programs.

398. The State of New York, by and through the New York Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

399. Compliance with applicable Medicare, Medicaid, and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the State of New York in connection with Defendants' conduct. Compliance with applicable New York statutes, regulations, and Pharmacy Manuals was also an express condition of payment of claims

submitted to the State of New York.

400. Had the State of New York known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.

401. As a result of Defendants' violations of the New York State False Claims Act, the State of New York has been damaged in an amount far in excess of millions of dollars, exclusive of interest.

402. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint and has brought this action pursuant to the New York State False Claims Act, on behalf of itself and the State of New York.

403. Relator requests this Court to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of New York, in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF NEW YORK:

(1) Three times the amount of actual damages which the State of New York has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $6,000 and not more than $12,000 for each false claim which Defendants caused to be presented to the State of New York;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATOR:

(1) The maximum amount allowed pursuant to the New York State False Claims Act, and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT XXII – NORTH CAROLINA FALSE CLAIMS ACT

(N.C.G.S.A. § 1-605, *et seq.*)

404. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

405. This is a *qui tam* action brought by Relator on behalf of the State of North Carolina to recover treble damages and civil penalties under the North Carolina False Claims Act, N.C.G.S.A. § 1-605, *et seq*.

406. In addition, N.C.G.S.A. § 108A-63 prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for furnishing any item or service for which payment may be made, in whole or in part, under the North Carolina Medicaid program.

407. Defendants violated the North Carolina False Claims Act by engaging in the conduct alleged herein.

408. Defendants further violated the North Carolina False Claims Act, and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of North Carolina, by their deliberate and systematic violation of federal and state laws, including the FCA, federal AKS and N.C.G.S.A. § 108A-63, and by virtue of the fact that none of the claims submitted in connection with their conduct were eligible for reimbursement by the Government Healthcare Programs.

409. The State of North Carolina, by and through the North Carolina Medicaid

program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

410. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the State of North Carolina in connection with Defendants' conduct. Compliance with applicable North Carolina statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of North Carolina.

411. Had the State of North Carolina known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.

412. As a result of Defendants' violations of the North Carolina False Claims Act, the State of North Carolina has been damaged in an amount far in excess of millions of dollars, exclusive of interest.

413. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint and has brought this action pursuant to the North Carolina False Claims Act, on behalf of itself and the State of North Carolina.

414. Relator requests this Court to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of North Carolina, in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following

damages to the following parties and against Defendants:

To the STATE OF NORTH CAROLINA:

(1) Three times the amount of actual damages which the State of North Carolina has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $12,537 and not more than $25,076 for each false claim which Defendants caused to be presented to the State of North Carolina;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATOR:

(1) The maximum amount allowed pursuant to North Carolina False Claims Act and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT XXIII – OKLAHOMA MEDICAID FALSE CLAIMS ACT

(63 Ok. St. Ann. § 5053, *et seq.*)

415. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

416. This is a *qui tam* action brought by Relator on behalf of the State of Oklahoma to recover treble damages and civil penalties under the Oklahoma Medicaid False Claims Act, 63 Okl. St. Ann. § 5053, *et seq*.

417. Defendants violated the Oklahoma Medicaid False Claims Act by engaging in the conduct alleged herein.

418. Defendants furthermore violated the Oklahoma Medicaid False Claims Act and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Oklahoma by their deliberate and systematic violation of federal

and state laws, including the FCA, federal AKS and 56 Okl. St. Ann. § 1005, and by virtue of the fact that none of the claims submitted in connection with their conduct were eligible for reimbursement by the Government Healthcare Programs.

419. The State of Oklahoma, by and through the Oklahoma Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

420. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the State of Oklahoma in connection with Defendants' conduct. Compliance with applicable Oklahoma statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Oklahoma.

421. Had the State of Oklahoma known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.

422. As a result of Defendants' violations of the Oklahoma Medicaid False Claims Act, the State of Oklahoma has been damaged in an amount far in excess of millions of dollars, exclusive of interest.

423. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint and has brought this action pursuant to the Oklahoma Medicaid False Claims Act, on behalf of itself and the State of Oklahoma.

424. Relator requests this Court to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely

asserts separate damages to the State of Oklahoma, in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF OKLAHOMA:

(1) Three times the amount of actual damages which the State of Oklahoma has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of Oklahoma;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATOR:

(1) The maximum amount allowed pursuant to Oklahoma Medicaid False Claims Act and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT XXIV– RHODE ISLAND FALSE CLAIMS ACT

(Gen. Laws 1956, § 9-1.1-1, *et seq.*)

425. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

426. This is a *qui tam* action brought by Relator on behalf of the State of Rhode Island to recover treble damages and civil penalties under the Rhode Island False Claims Act, Gen. Laws 1956, § 9-1.1-1, *et seq.*

427. Defendants violated the Rhode Island False Claims Act by engaging in the conduct alleged herein.

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428. Defendants further violated the Rhode Island False Claims Act and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Rhode Island by their deliberate and systematic violation of federal and state laws, including the FCA, federal AKS and Gen. Laws 1956, § 40-8.2-9, and by virtue of the fact that none of the claims submitted in connection with their conduct were eligible for reimbursement by the Government Healthcare Programs.

429. The State of Rhode Island, by and through the Rhode Island Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

430. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the State of Rhode Island in connection with Defendants' conduct. Compliance with applicable Rhode Island statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Rhode Island.

431. Had the State of Rhode Island known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.

432. As a result of Defendants' violations of the Rhode Island False Claims Act, the State of Rhode Island has been damaged in an amount far in excess of millions of dollars, exclusive of interest.

433. Relator is a private citizen with direct and independent knowledge of the

allegations of this Complaint and has brought this action pursuant to the Rhode Island False Claims Act, on behalf of itself and the State of Rhode Island.

434. Relator requests this Court to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of Rhode Island, in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF RHODE ISLAND:

(1) Three times the amount of actual damages which the State of Rhode Island has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $12,537 and not more than $25,076 for each false claim which Defendants caused to be presented to the State of Rhode Island;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATOR:

(1) The maximum amount allowed pursuant to Rhode Island False Claims Act and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT XXV – TENNESSEE MEDICAID FALSE CLAIMS ACT

(Tenn. Code Ann. § 71-5-181, *et seq.*)

435. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

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436. This is a *qui tam* action brought by Relator on behalf of the State of Tennessee to recover treble damages and civil penalties under the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181, *et seq*.

437. Defendants violated Tenn. Code Ann. § 71-5-182(a)(1) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Tennessee by their deliberate and systematic violation of federal and state laws, including the FCA and AKS, and by virtue of the fact that none of the claims submitted in connection with their conduct were eligible for reimbursement by the Government Healthcare Programs.

438. The State of Tennessee, by and through the Tennessee Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

439. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the State of Tennessee in connection with Defendants' conduct. Compliance with applicable Tennessee statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Tennessee.

440. Had the State of Tennessee known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.

441. As a result of Defendants' violations of Tenn. Code Ann. § 71-5-182(a)(1), the State of Tennessee has been damaged in an amount far in excess of millions of dollars, exclusive of interest.

442. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Tenn. Code Ann. § 71-5-183(a)(1), on behalf of himself/herself and the State of Tennessee.

443. Relator requests this Court to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damaged to the State of Tennessee, in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF TENNESSEE:

(1) Three times the amount of actual damages which the State of Tennessee has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $5,000 and not more than $25,000 for each false claim which Defendants caused to be presented to the State of Tennessee;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATOR:

(1) The maximum amount allowed pursuant to Tenn. Code Ann. § 71-5-183(c) and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

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COUNT XXVI – TEXAS MEDICAID FRAUD PREVENTION ACT (V.T.C.A. Hum. Res. Code § 36.001, *et seq.*)

444. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

445. This is a *qui tam* action brought by Relator on behalf of the State of Texas to recover civil remedies and civil penalties under V.T.C.A. Hum. Res. Code § 36.001, *et seq.*

446. Defendants knowingly committed multiple unlawful acts as defined in the applicable version of the V.T.C.A. Hum. Res. Code § 36.002 and § 32.039(b) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Texas by their deliberate and systematic violation of federal and state laws, including the FCA, federal AKS and § 36.002, and by virtue of the fact that none of the claims submitted in connection with their conduct were eligible for reimbursement by the Government Healthcare Programs.

447. Defendant knowingly made or caused to be made false statements or misrepresentations of material fact on or after October 2013 submitted to Texas Medicaid. Defendant's false statements or misrepresentations permitted Defendant to receive benefits under the Texas Medicaid program that were not authorized or that were greater than the benefits authorized. In doing so, Defendants violated Texas Human Resources Code § 36.002(1).

448. Defendant knowingly concealed information from or failed to disclose information to Texas Medicaid regarding Defendants' remuneration to induce healthcare providers to treat Texas Medicaid cardiac patient beneficiaries with Abbott's MitraClip device. Additionally, Defendant knowingly concealed or failed to disclose to Texas Medicaid that Defendant was not in compliance with Texas laws and regulations, despite affirmations to the contrary. This conduct permitted Defendant to receive benefits under

the Texas Medicaid program that were greater than the benefits authorized. In doing so Defendant violated Texas Human Resources Code § 36.002(2).

449. Defendant knowingly made, caused to be made, induced, or sought to induce, the making of false statements or misrepresentations of material facts concerning information required to be provided by a state law, rule, regulation, or provider agreement pertaining to the Texas Medicaid program. In doing so, Defendant violated Texas Human Resources Code § 36.002(4)(B).

450. Defendant knowingly offered or paid, directly or indirectly, overtly or covertly, remuneration, including kickbacks, bribes, or rebates, in cash or in kind, to induce a person to purchase or order, or to arrange for or to recommend the purchase or order of, any good, facility, service, or item for which payment may be made, in whole or in part, under the Texas Medicaid program. Defendant offered remuneration in the form of, *inter alia*, speaker programs and participation in device trials to Texas healthcare providers with the intention of obtaining Texas heathcare Medicaid business. In doing so, Defendant violated Texas Human Resources Code § 32.039(b) and therefore Texas Human Resources Code § 36.002(13) as well.

451. As a result of Defendant's unlawful acts, Defendant directly or indirectly obtained payments or monetary or in-kind benefits from the Texas Medicaid program to which it was not entitled.

452. The State of Texas, by and through the Texas Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

453. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the State of Texas in connection with Defendants' conduct. Compliance with applicable Texas statutes, regulations and

Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Texas.

454. Had the State of Texas known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.

455. As a result of Defendants' violations of V.T.C.A. Hum. Res. Code § 36.002 and § 32.039(b), the State of Texas has been damaged in an amount far in excess of millions of dollars, exclusive of interest.

456. Defendants did not, within 30 days after it first obtained information as to such violations, furnish such information to officials of the State of Texas responsible for investigating false claims violations, did not otherwise fully cooperate with any investigation of the violations, and have not otherwise furnished information to the State of Texas regarding the claims for reimbursement at issue.

457. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to V.T.C.A. Hum. Res. Code § 36.101, on behalf of itself and the State of Texas.

458. Relator requests this Court to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate remedies and penalties to the State of Texas, in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following civil remedies and penalties to the following parties and against Defendants:

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To the STATE OF TEXAS:

(1) Plaintiffs seek an additional two times the value of all payments or monetary or in-kind benefits provided to Defendant under the Medicaid program as a result of Defendant's unlawful acts, pursuant to Texas Human Resources Code § 36.052(a)(4);

(2) A civil penalty of not less than $12,537 and not more than $25,076 pursuant to V.T.C.A. Hum. Res. Code § 36.052(a)(3);

(3) Plaintiffs seek recovery of the value of all payments or monetary or in-kind benefits provided to Defendant under the Medicaid program as a result of Defendant's unlawful acts, together with pre-judgment and post-judgment interest, pursuant to Texas Human Resources Code § 36.052(a)(1) and (2).; and

(4) All costs incurred in bringing this action.

To RELATOR:

(1) The maximum amount allowed pursuant to V.T.C.A. Hum. Res. Code § 36.110, and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT XXVII – VIRGINIA FRAUD AGAINST TAX PAYERS ACT

(§ 8.01-216-3a)

459. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

460. This is a *qui tam* action brought by Relator on behalf of the Commonwealth of Virginia for treble damages and penalties under Virginia Fraud Against Tax Payers Act, §8.01-216.3a.

461. Defendants violated VA Code Ann. § 32.1-315 by engaging in the conduct

alleged herein.

462. Defendants furthermore violated Virginia's Fraud Against Tax Payers Act, § 8.01-216.3a, and knowingly caused hundreds of thousands of false claims to be made, used and presented to the Commonwealth of Virginia by their deliberate and systematic violation of federal and state laws, including the FCA, federal AKS, VA Code Ann. § 32.1-315 and by virtue of the fact that none of the claims submitted in connection with their conduct were eligible for reimbursement by the Government Healthcare Programs.

463. The Commonwealth of Virginia, by and through the Virginia Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

464. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the Commonwealth of Virginia in connection with Defendants' conduct. Compliance with applicable Virginia statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the Commonwealth of Virginia.

465. Had the Commonwealth of Virginia known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.

466. As a result of Defendants' violations of Virginia's Fraud Against Tax Payers Act, §8.01-216.3a, the Commonwealth of Virginia has been damaged in an amount far in excess of millions of dollars, exclusive of interest.

467. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, and has brought this action pursuant to Virginia's Fraud Against Tax Payers Act, §8.01-216.3, on behalf of itself and the Commonwealth of Virginia.

468. Relator requests this Court to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the Commonwealth of Virginia, in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the COMMONWEALTH OF VIRGINIA:

(1) Three times the amount of actual damages which the Commonwealth of Virginia has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $12,537 and not more than $25,076 for each false claim which Defendants caused to be presented to the Commonwealth of Virginia;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATOR:

(1) The maximum amount allowed pursuant to VA Code Ann. § 32.1-315 and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

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COUNT XXVIII - WASHINGTON STATE MEDICAID FRAUD FALSE CLAIMS ACT

(RCWA 74.66.005, *et seq.*)

469. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

470. This is a *qui tam* action brought by Relator on behalf of the State of Washington to recover treble damages and civil penalties under the Washington State Medicaid Fraud False Claims Act, RCWA 74.66.005, *et seq*.

471. Defendants violated RCWA 74.09.240 by engaging in the conduct described herein.

472. Defendants furthermore violated the Washington State Medicaid Fraud False Claims Act, RCWA 74.66.005, *et seq*., and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Washington, by their deliberate and systematic violation of federal and state laws, including the FCA, federal AKS, and RCWA 74.09.240, and by virtue of the fact that none of the claims submitted in connection with their conduct were eligible for reimbursement by the Government Healthcare Programs.

473. The State of Washington, by and through the Washington Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

474. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the State of Washington in connection with Defendants' conduct. Compliance with applicable Washington statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to

1 the State of Washington.
2 475. Had the State of Washington known that Defendants were violating the
3 federal and state laws cited herein and/or that the claims submitted in connection with
4 Defendants' conduct failed to meet the reimbursement criteria of the Government
5 Healthcare Programs or were premised on false and/or misleading information, it would
6 not have paid the claims submitted by healthcare providers and third-party payers in
7 connection with that conduct.
8 476. As a result of Defendants' violations of the Washington State Medicaid Fraud
9 False Claims Act, RCWA 74.66.005, *et seq*., the State of Washington has been damaged
10 in an amount far in excess of millions of dollars, exclusive of interest.
11 477. Relator is a private citizen with direct and independent knowledge of the
12 allegations of this Complaint, and has brought this action pursuant to the Washington State
13 Medicaid Fraud False Claims Act, RCWA 74.66.005, *et seq*., on behalf of itself and the
14 State of Washington.
15 478. Relator requests this Court to accept pendant jurisdiction of this related state
16 claim as it is predicated upon the exact same facts as the federal claim, and merely asserts
17 separate damages to the State of Washington, in the operation of its Medicaid program.
18 WHEREFORE, Relator respectfully requests this Court to award the
19 following damages to the following parties and against Defendants:
20 To the STATE OF WASHINGTON:
21 (1) Three times the amount of actual damages which the State of
22 Washington has sustained as a result of Defendants' conduct;
23 (2) A civil penalty of not less than $12,537 and not more than $25,076 for each false claim which Defendants caused to be presented to the State
24 of Washington;
25 (3) Prejudgment interest; and
26 (4) All costs incurred in bringing this action.
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To RELATOR:

(1) The maximum amount allowed pursuant to the Washington State Medicaid Fraud False Claims Act, RCWA 74.66.005, *et seq*., and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT XXIX – D.C. FALSE CLAIMS ACT

(D.C. Code § 2-381.01, *et seq.*)

479. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

480. This is a *qui tam* action brought by Relator and the District of Columbia to recover treble damages and civil penalties under the District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-381.01, *et seq.*

481. Defendants violated D.C. Code § 4-802(c) by engaging in the illegal conduct alleged herein.

482. Defendants further violated D.C. Code § 2-381.02 and knowingly caused thousands of false claims to be made, used and presented to the District of Columbia by their deliberate and systematic violation of federal and state laws, including the FCA, federal AKS, D.C. Code § 4-802(c), and by virtue of the fact that none of the claims submitted in connection with their illegal conduct were eligible for reimbursement by the Government Healthcare Programs.

483. The District of Columbia, by and through the District of Columbia Medicaid program and other District of Columbia healthcare programs, and unaware of Defendants' illegal conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

484. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the District of Columbia in connection with Defendants' illegal conduct. Compliance with applicable District of Columbia statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the District of Columbia.

485. Had the District of Columbia known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.

486. As a result of Defendants' violations of D.C. Code § 2-381.02, the District of Columbia has been damaged in an amount far in excess of millions of dollars, exclusive of interest.

487. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint and has brought this action pursuant to D.C. Code § 2-381.03(b) on behalf of itself and the District of Columbia.

488. Relator requests this Court to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the District of Columbia, in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the DISTRICT OF COLUMBIA:

(1) Three times the amount of actual damages which the District of

1 Columbia has sustained as a result of Defendants' illegal conduct;

2 (2) A civil penalty of not less than $5,500 and not more than $11,000 for
3 each false claim which Defendants caused to be presented to the District of Columbia;

4 (3) Prejudgment interest; and

5 (4) All costs incurred in bringing this action.

6 To RELATOR:

7 (1) The maximum amount allowed pursuant to D.C. Code § 2-381.03
8 and/or any other applicable provision of law;

9 (2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

10 (3) An award of reasonable attorneys' fees and costs; and

11 (4) Such further relief as this Court deems equitable and just.

12 **PRAYER FOR RELIEF**

13 WHEREFORE, Relator, on behalf of the United States and the States of California,
14 Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa,
15 Louisiana, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New
16 York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, and
17 Washington, along with the District of Columbia, demands that judgment be entered in
18 their favor and against Defendants for the maximum amount of damages and such other
19 relief as the Court may deem appropriate on each Count. This includes, with respect to
20 the federal False Claims Act, three times the amount of damages, civil remedies, and
21 penalties to the Federal Government plus civil penalties of no more than Eleven
22 Thousand Dollars ($11,000.00) and no less than Five Thousand Five Hundred Dollars
23 ($5,500.00) for each false claim on or before November 2, 2015, and civil penalties of no
24 more than Twenty-Five Thousand and Seventy-Six Dollars ($25,076.00) and not less
25 than Twelve Thousand Five Hundred and Thirty-Seven Dollars ($12,537.00) for each
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false claim after November 2, 2015, and any other recoveries or relief provided for under the Federal False Claims Act.

Finally, Relator requests that he/she receive the maximum amount permitted by law of the proceeds of this action or settlement of this action collected by the United States and the Plaintiff-States, plus reasonable expenses necessarily incurred, and reasonable attorneys' fees and costs. Relator requests that his/her award be based upon the total value recovered, both tangible and intangible, including any amounts received from individuals or entities not parties to this action.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator demands a trial by jury on all Counts.

Respectfully submitted,

MILLER SHAH LLP

Dated: May 23, 2023

/s/ Chiharu G. Sekino

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