UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA EX REL.TERESA ROSS, Plaintiff, v. INDEPENDENT HEALTH ASSOCIATION, INDEPENDENT HEALTH CORPORATION, DxID LLC, & BETSY GAFFNEY, Defendants.	CASE NO. 12-CV-0299(S)

UNITED STATES' COMPLAINT IN INTERVENTION

The United States of America ("United States" or "Government") brings this action against Defendants Independent Health Association ("IHA") and Independent Health Corporation ("IHC") (collectively "IH"), DxID LLC ("DxID"), and Betsy Gaffney ("Gaffney") (collectively, "Defendants"), to recover treble damages and civil penalties for their violations of the False Claims Act ("FCA"), 31 U.S.C. §§ 3729–3733, and damages and other relief for their common law violations of payment by mistake and unjust enrichment. Having filed a concurrent notice of intervention pursuant to 31 U.S.C. § 3730(b)(4), the United States alleges for its complaint-in-intervention ("Complaint") the following:

PRELIMINARY STATEMENT

1. Defendants' violations of the FCA arise from IH's and DxID's participation in the Medicare Advantage ("MA") Program, which is a Medicare program administered by the Centers for Medicare & Medicaid Services ("CMS"). As set forth below, Defendants violated the FCA by knowingly submitting or causing to be submitted thousands of false claims,

statements, and records to the Government in connection with the MA Program.

2. Specifically, Defendants (1) knowingly submitted or caused to be submitted thousands of unsupported diagnosis codes to CMS, (2) knowingly used or caused to be used false records or statements to submit the unsupported diagnosis codes, (3) knowingly retained overpayments resulting from the submission of these unsupported diagnosis codes, and (4) conspired with the other defendants to violate the FCA from no later than January 1, 2011 through at least January 31, 2017.

3. Defendant IH is a MA Organization ("MAO") that contracted with CMS to provide MA health plans to beneficiaries enrolled in Medicare Part C in New York State. Generally, under the MA Program, CMS pays insurers, like IH, on a per member per month ("PMPM") or capitated basis. CMS calculates and increases payments to insurers, like IH, pursuant to a risk adjustment system, in which payment increases are based, in part, on the health status of the plan's members. Thus, CMS pays more for sicker members and for members who have conditions that are costlier to manage than for healthier members. Therefore, the submission of diagnosis codes directly affects the amount of payments to MAOs like IH.

4. CMS requires the submission of accurate diagnosis codes that are properly documented. Accurate diagnosis codes are fundamental to accurate payments from the Government to MAOs in the MA Program. As the Court of Appeals for the District of Columbia recently recognized, "Payments to the Medicare Advantage program depend on participating insurers accurately reporting to CMS their beneficiaries' salient demographic information and medically documented diagnosis codes." *UnitedHealthcare Ins. Co. v. Becerra*, No. 18-5326, 2021 U.S. App. LEXIS 24141, at *3 (D.C. Cir. Aug. 13, 2021).

5. Defendants obtained higher payments by implementing a risk adjustment program that, in effect, made it appear that enrollees in MA Plans that DxID serviced, including IH and another MAO called Group Health Cooperative ("GHC"), were sicker than was documented by the enrollees' health care provider in their medical records.

6. To execute this fraud scheme, IH created DxID, which was headed by Defendant Gaffney, to provide "HCC[1] Management and Medical Record Document Management Solutions" for IH, GHC, and other MAOs. DxID instituted a retrospective medical records review program that allowed it to reach back into the medical records of MA Plan enrollees and thereby "capture" conditions that were purportedly missed by providers or previous coders. IH and GHC submitted these newly captured codes to CMS and increased their PMPM payments. DxID, in turn, received a share of up to 20 percent of the additional revenue that its program achieved for the MAOs.

7. DxID's services were designed to capture and cause the submission of diagnosis codes that were not accurate or adequately documented in medical records. *See* 42 C.F.R. § 422.504 (requiring accurate, complete, and truthful data for risk adjustment). Under prevailing rules, MAOs are instructed to "[c]ode all documented conditions that coexist at the time of the encounter/visit, and require or affect patient care, treatment or management." *See* 42 C.F.R. § 162.1002(c) (adopting the ICD as the standard medical data code set); ICD-10-CM Official Guidelines for Coding and Reporting FY 2014 ("FY14 ICD-10 Coding Guidelines") at 104, *available at* https://www.cdc.gov/nchs/data/icd/icd10cm_guidelines_2014.pdf.

[1] HCC refers to Hierarchical Condition Categories. HCCs are sets of medical codes that are linked to specific clinical diagnoses. HCCs are used by CMS as part of a risk adjustment model and affect payment to MAO, as discussed in depth below.

8. DxID, however, captured thousands of diagnosis codes that it knew did not meet this standard.

9. IH received ample warning about the impropriety of DxID's coding policies and that DxID's aggressive coding approach would cause submission of unsupported diagnosis codes.

10. GHC also used DxID's services at the recommendation of IH and submitted to CMS unsupported diagnoses codes that DxID captured.

11. Defendants accomplished their scheme primarily in two ways: (1) a retrospective chart review program and (2) an addenda process.

12. First, DxID implemented a retrospective chart review program, in which it re-reviewed enrollees' medical records—often after several levels of review had already occurred, including the original entry by the provider, the coding and submission of claims by the provider to the MAO, an initial review and coding by the plan, and secondary review by the plan or its vendor—to search for additional diagnosis codes to submit for risk adjustment.

13. During these retrospective chart reviews, however, DxID recklessly disregarded the requirement that a condition for which a diagnosis code is submitted must be documented as relevant to patient care, treatment, or management during a visit or encounter in the date of service ("DOS") year[2], and not merely mentioned in records from prior years, suggested by computer algorithm, or inferred anywhere on an outpatient medical record.[3]

[2] The date of service ("DOS") year is the calendar year that a patient had a visit or encounter with his or her provider. CMS uses the diagnosis codes from the DOS year to calculate the risk adjustment for that beneficiary in the next calendar year, which is often called the payment or plan year ("PY").

[3] For brevity, the coding standard, as promulgated by ICD and adopted by CMS, is further described in this complaint as requiring that coded conditions be documented in the medical record as relevant

14. IH participated in the retrospective chart review program for DOS years 2010 through at least 2017. DxID, Gaffney, and IH also caused GHC to submit unsupported diagnosis codes using the retrospective chart review program for DOS years 2010 and 2011.[4]

15. Second, DxID implemented an "addenda process" whereby it nudged providers to retroactively add diagnoses—up to 12 months after an encounter—to medical records that they purportedly missed during the patient encounter, so that DxID could capture, and IH could submit, additional diagnosis codes.

16. To accomplish this part of the scheme, DxID used leading and suggestive forms to nudge providers to sign off on diagnoses, often without any basis, that DxID suggested the provider assessed during an encounter but did not adequately document in the medical records. These included conditions on problem lists or from lab results that the health care provider may not have reviewed at all or conditions that DxID simply predicted that a patient should have based on its algorithm or simply Gaffney's say so. For example, Gaffney advocated for adding Chronic Kidney Disease ("CKD") to most requests for addenda to providers, regardless of whether there was any indication that the beneficiary had CKD, because Gaffney believed that "[p]retty much everyone over age 70 has some level of CKD."

17. DxID also sent these requests for addenda to providers many months after the patient encounter. Despite having actual notice that this practice was inherently unreliable, that providers accepted DxID's recommended diagnoses, and that DxID's addenda process did, in fact, lead to submissions of undocumented diagnosis codes, DxID and IH used the

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to patient care during an encounter in the DOS year. This description is intended to incorporate the full scope of the ICD Guidelines.

[4] GHC was a named defendant in the original *qui tam* action. GHC settled in November 2020. *See* ECF No. 125.

addenda process to capture and submit over 125,000 diagnosis codes that resulted in CMS paying millions of dollars more to IH than it would have otherwise paid.

18. Unlike IH, GHC recognized the impropriety of the addendum process promoted by DxID and refused to participate in that part of the scheme.

19. Each unsupported diagnosis code that IH, DxID, or Gaffney knowingly submitted, or caused to be submitted, and that was used in the calculation of CMS's risk adjustment payments is a false claim under the FCA.

20. Furthermore, MAO's are required to attest to the accuracy of their risk adjustment data, and therefore each attestation that IH submitted with knowledge that its data was not accurate is a false statement in support of false claims under the FCA.

21. As a result, Defendants unlawfully obtained and retained from CMS millions of dollars in payments under Medicare Part C's risk-adjusted payment system.

22. Accordingly, this scheme gives rise to FCA claims against IHA, IHC, DxID, and Gaffney for knowingly submitting and/or causing the submission of false claims in violation of 31 U.S.C. § 3729(a)(1)(A); for knowingly using and/or causing the use of false records and statements material to false claims in violation of 31 U.S.C. § 3729(a)(1)(B); for knowingly using and/or causing the use of false records and statements material to the obligation to repay overpayments in violation of 31 U.S.C. § 3729(a)(1)(G) and knowingly avoiding the obligation to repay overpayments in violation of 31 U.S.C. § 3729(a)(1)(G); and for conspiring to violate sections 3729(a)(1)(A), (B), & (G) in violation of 31 U.S.C. § 3729(a)(1)(C). In addition, Defendants are liable to the United States for the common law causes of action of payment by mistake and unjust enrichment.

THE PARTIES

23. Plaintiff is the United States of America, suing on behalf of the United States Department of Health and Human Services ("HHS"), which includes its operating division, CMS. At all times relevant to this Complaint, CMS administered and supervised the Medicare Part C Program and made risk adjustment payments under Part C of the Program.

24. The *qui tam* relator, Teresa Ross, filed an action alleging violations of the FCA on behalf of herself and the United States Government pursuant to the *qui tam* provisions of the FCA on April 11, 2012 (ECF No. 1) and a First Amended Complaint on February 5, 2016 (ECF No. 32). Ross is a citizen of the United States and a resident of Puyallup, Washington. Ross was employed by GHC for over 14 years. At the end of her employment, Ross was the Director of Risk Adjustment Services. Prior to that, Ross was the Director of Insurance and Health Data Analysis ("IHDA"). As Director of IHDA, Ross implemented the standard risk adjustment claims verification procedures used by GHC and developed algorithms to identify and correct diagnosis-coding issues and ensure accurate and complete risk adjustment claims submissions. Ross gained knowledge and experience of the Medicare risk adjustment system from directing and implementing risk adjustment programs at GHC. Ross has personal knowledge of the fraud that DxID conducted at GHC. On or about February 26, 2013, Ross left GHC for another position.

25. Defendant Independent Health Association ("IHA") is a non-profit corporation with headquarters in Buffalo, New York. IHA offers two MA Plans in New York State.

26. Defendant Independent Health Corporation ("IHC") is a for-profit subsidiary of IHA. IHA controls IHC, including through overlapping corporate governance boards and

executive officers.

27. Defendant DxID is a New York Limited Liability Company. DxID is a subsidiary of IHC. Among other things, DxID provided risk adjustment and chart review services to MA Plans, including those managed by IHA and GHC. DxID recently ceased operations.[5]

28. Defendant Gaffney was the founder and CEO of DxID. Prior to DxID, Gaffney was a principal at Cognisight, where she provided retrospective chart review services for risk-adjusted payments to IH. She continued providing the retrospective chart review services to IH and other MAOs when she formed DxID.

JURISDICTION AND VENUE

29. This Court has subject matter jurisdiction over this action per 28 U.S.C. § 1345 because the United States is the plaintiff. In addition, the Court has subject matter jurisdiction over FCA claims for relief under 31 U.S.C. § 3732(a) and (b).

30. This Court has personal jurisdiction over Defendants under 31 U.S.C. § 3732(a) because at least one of the defendants can be found in, resides in, and transacts business in this District, or has committed the alleged acts in this District.

31. Venue lies in this District under 28 U.S.C. § 1391(b) and (c) and 31 U.S.C. § 3732(a) because Defendants can be found in and transact business in this District, a substantial part of the events or omissions giving rise to the claims occurred in this District, and all of the defendants are subject to the Court's jurisdiction under the FCA.

[5] https://www.independenthealth.com/dxid.

THE FALSE CLAIMS ACT

32. The FCA is the primary civil remedial statute designed to deter fraud upon the United States and reflects Congress' objective to "enhance the Government's ability to recover losses as a result of fraud against the Government." S. Rep. 99-345 (1986), at 1, as reprinted in 1986 U.S.C.C.A.N. 5266. "The Medicare Advantage capitation payment system is subject to the False Claims Act." *United States ex rel. Silingo v. WellPoint, Inc.*, 904 F.3d 667, 673 (9th Cir. 2018).

33. First, a defendant violates the FCA when it "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). As it relates to this case, the term "claim" under § 3729(b)(2) of the FCA includes "(A) . . . any request or demand, whether under a contract or otherwise, for money . . . that . . . (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 . . . requested or demanded; or (II) will reimburse such contractor, grantee, or other recipient for any portion of the money which is requested or demanded." *Id.* § 3729(b)(2).

34. Second, a defendant violates the FCA when it "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." *Id.* § 3729(a)(1)(B).

35. Third, a defendant violates the FCA when it "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."

Id. § 3729(a)(1)(G). The FCA defines the term "obligation" to include "the retention of any overpayment." *Id.* § 3729(b)(3).

36. Upon learning of an unsupported diagnosis code resulting in an MA overpayment from CMS, the MAO has the duty to delete or otherwise withdraw that code. *See United States ex rel. Swoben v. United Healthcare Ins. Co.*, 848 F.3d 1161, 1176-77 & n.8 (9th Cir. 2016). Deletion of the unsupported diagnosis codes would result in CMS's electronic processing system recalculating the payment amount, which is CMS's first step in recouping the overpayment. Thus, the failure to delete or withdraw these unsupported codes after notice thereof constitutes the knowing retention of an overpayment in violation of 31 U.S.C. § 3729(a)(1)(G).

37. Fourth, a defendant violates the FCA when it "conspires to commit a violation of" 31 U.S.C. § 3729(a)(1)(A), (B), & (G). *Id.* § 3729(a)(1)(C).

38. Under the FCA, the terms "knowing" and "knowingly" include "actual knowledge of the information," "deliberate ignorance of the truth or falsity of the information," or "reckless disregard of the truth or falsity of the information," and "require no proof of specific intent to defraud." 31 U.S.C. § 3729(b)(1)(A),(B). Congress intended the terms "knowing" and "knowingly" to "reach what has become known as the 'ostrich' type situation where an individual has 'buried his head in the sand' and failed to make simple inquiries which would alert him that false claims are being submitted." S. Rep. No. 99-345 (1986), at 21, as reprinted in 1986 U.S.C.A.N. 5266, 5286 (quotations in original.) "It is intended that persons who ignore 'red flags' that the information may not be accurate or those persons who deliberately choose to remain ignorant of the process through which their company handles a claim should be held liable under the Act." H. Rep. No. 99-660, at 21

(1986) (to accompany False Claims Act of 1986, H.R. 4827). As used in this Complaint, the terms "knowing" and "knowingly" have the meaning ascribed to them by the FCA, as do their derivatives "knowledge," "known," and "knew."

39. The term "material," as used in the FCA, "means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4).

40. The FCA imposes liability of treble damages plus a civil penalty for each false claim in an amount (as pertinent here) not less than $5,500 and not more than $11,000 for claims submitted prior to August 1, 2016; not less than $10,781 and not more than $21,563 for claims submitted between August 1, 2016 and January 29, 2018, and as appropriately statutorily adjusted for inflation each successive year under the Bipartisan Budget Act of 2015, Pub. L. 114-74, § 701, 129 Stat. 584, 599-601 (2015). *See* 31 U.S.C. § 3729(a)(1).

THE MEDICARE ADVANTAGE PROGRAM

41. Medicare is a federally operated health insurance program administered by CMS benefiting individuals 65 and older and the disabled. *See* 42 U.S.C. § 1395c.

42. Parts A and B of the Medicare Program are known as "traditional" Medicare. Part A covers inpatient and institutional care. Part B covers physician, hospital, outpatient, and ancillary services and durable medical equipment. In the traditional Medicare program, Parts A and B, CMS reimburses health care providers for benefits covered under Medicare Parts A and B. Parts A and B use the fee-for-service system, in which providers submit claims to CMS for healthcare services actually rendered, such as a physician office visit or hospital stay. CMS then pays the providers directly for each service based on payment rates pre-determined by the Government.

43. Under Medicare Part C, which is at issue in this case, Medicare beneficiaries may opt out of traditional Medicare and instead enroll in MA Plans to receive healthcare services managed by those Plans. *See* 42 U.S.C. §§ 1395w-21 to 1395w-28. MA Plans are run by private insurers known as MA Organizations ("MAOs"). *See* 42 C.F.R. §§ 422.2, 422.503(b)(2).

44. Under Medicare Part C, MAOs contract with CMS to provide services to people who are eligible for Medicare. *See* 42 U.S.C. §§ 1395w-21-1395w-28. MAOs provide coverage that is at least equivalent to Parts A and B.

45. Many MAOs contract with hospital networks, physician groups, and other providers to furnish healthcare services under the MA Plans.

46. MA Plans come in a variety of forms. Some MA Plans are structured like a Preferred Provider Organization ("PPO") that offers a network of healthcare providers that a beneficiary can use for medical care and may see a specialist without a referral. Other MA Plans are structured like a Health Maintenance Organization ("HMO"), in which a MAO organizes a network of healthcare providers that a beneficiary may go to for healthcare services, and the beneficiary's primary care physician serves as the central point of contact.

47. IH, based in New York, is an MAO that contracts with CMS and, between at least 2011 and 2018, offered two MA Plans with non-employee providers.[6] IH operates its MA Plans as PPOs. *See* Exs. A, B.[7]

48. GHC, based in Washington State, was an MAO that, between at least 2010

[6] IH's MA Plans are Independent Health Association, Inc. and Independent Health Benefits Corporation.

[7] Ex. A are the CMS's contracts with Independent Health Benefits Corporations and Ex. B are CMS's contracts with Independent Health Association, Inc.

and 2012, contracted with CMS to offer an MA Plan. GHC operated its MA Plan as HMOs, whereby it owned and operated its own clinics with employee physicians and nurses. *See* Ex. C.

49. DxID performed HCC Management and Medical Record Document Management Solutions, involving retrospective medical record reviews, including an addenda process, for IH's MA Plan's submissions to CMS beginning in 2011 for DOS years 2010 through at least 2017. *See* Ex. D.

50. At the recommendation of IH, GHC contracted with DxID to perform HCC Management and Medical Record Document Management Solutions to assist in the submissions to CMS starting in 2011 for DOS years 2010 and 2011. *See* Ex. E.

51. Pursuant to Medicare regulations, DxID is a "related entity." *See* 42 C.F.R. § 422.500(b). A related entity is an "entity that is related to the MA organization by common ownership or control and (1) [p]erforms some of the MA organization's management functions under contract or delegation; [or] (2) [f]urnishes services to Medicare enrollees under an oral or written agreement . . . ." *Id.*

52. Related entities, such as DxID, must, among other things, comply with the MAO's contractual obligations to the Government, 42 C.F.R. § 422.504(i)(3)(iii); agree to "comply with all applicable Medicare laws, regulations, and CMS instructions," *id.* at § 422.504(i)(4)(v); and receive effective compliance training and education relating to preventing fraud, waste, and abuse, *id.* § 422.503(b)(4)(vi)(C)(1). Furthermore, if a related entity generates data relating to an MAO's claims for payments from the MA Program, it must certify the accuracy and truthfulness of that data. *Id.* § 422.504(l)(3).

53. CMS has the authority to issue rules to implement and regulate Medicare Part

C. *See* 42 U.S.C. § 1395w-26(b). CMS has promulgated regulations that define the MAO's obligations and responsibilities. *See generally* 42 C.F.R. § 422.

54. As discussed more fully below, CMS's Part C regulations require MAOs, like IH and GHC, to "certify (based on best knowledge, information, and belief) that the [risk adjustment] data it submits . . . are accurate, complete, and truthful." 42 C.F.R. § 422.504(l)(2); *see also Silingo*, 904 F.3d at 673 (quoting the same). CMS also requires MAOs "to '[a]dopt and implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with CMS' program requirements,' such as written standards of conduct, the designation of a compliance officer, and other listed minimum requirements." *Silingo*, 904 F.3d at 673 (quoting 42 C.F.R. § 422.503(b)(4)(vi)).

55. MAOs' obligations to submit accurate diagnoses—as interpreted by the rules, regulations, guidelines, and guidance—are required by statute, as well as by contract. To participate in Medicare Part C, MAOs must execute a written agreement and an annual renewal of the written agreement with CMS for each of the Part C plans they operate. *See* 42 C.F.R. § 422.504 (describing mandatory provisions of the "contract between the MA organization and CMS" and that "[c]ompliance with the terms of this paragraph (a) is material to the performance of the MA contract."); 42 C.F.R. § 422.505 (describing renewal of contract).

56. As relevant here, IH executed such agreements or renewals annually for the MA Plans it operated from at least 2011 to 2018. *See generally* Exs. A and B.

57. GHC executed such agreements or renewals annually for the MA Plan it operated from at least 2011 to 2012. *See generally* Ex. C.

58. "The contract between the MA organization and CMS must contain" an

agreement by the MAO "to comply with all the applicable requirements and conditions set forth in this part and in general instructions." 42 C.F.R. § 422.504(a). And "[n]otwithstanding any relationship(s) that the MA organization may have with first tier, downstream, and related entities, the MA organization maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contracts with CMS." 42 C.F.R. § 422.504(i)(1).

59. "As a condition for receiving monthly payment under subpart G of this part, the MA organization agrees that its chief executive officer (CEO) . . .must request payment under the contract on a document that certifies . . . the accuracy, completeness, and truthfulness of relevant data that CMS requests," including "enrollment information, encounter data, and other information that CMS may specify." 42 C.F.R. § 422.504(l). Federal regulations further require the MAO to "certify . . . that the information provided for purposes of reporting and returning of overpayments . . . is accurate, complete, and truthful." 42 C.F.R. § 422.504(l)(5).

60. IH is therefore further required under its contract with CMS for offering MA Plans to comply "with the requirements of [the] contract and applicable Federal statutes, regulations, and policies (e.g., policies as described in the Call Letter, Medicare Managed Care Manual, etc.)." *See, e.g.*, Ex. A at 2, 9. By contract, IH agreed to "comply with all applicable requirements as described in CMS regulations and guidance implementing the Medicare Improvements for Patients and Providers Act of 2008." *Id.* at Art. II, Sec. E. The contract that IH signed was "deemed to incorporate any changes that are required by statute to be implemented during the term of the contract and any regulations or policies implementing or interpreting such statutory provision." *Id.* at Art. II, Sec. B.

61. As alleged above, federal regulations require that related entities like DxID "must comply with applicable Medicare laws, regulations, and CMS instructions." *See* 42 C.F.R. § 422.504(i)(4)(v). Likewise, under its contract with IH, DxID agreed that "DxID and any related entity, contractor or subcontractor will comply with all applicable Medicare laws, regulations, and CMS instructions," citing 42 C.F.R. § 422.504(i)(4)(v).

62. The terms and conditions in the Part C annual agreements/renewals that are relevant here have remained the same during that period.

63. Submitting unsupported diagnosis codes, including through the use of retrospective chart review program and supplementing the program with addenda, also constitutes a breach of contract as further alleged below.

MEDICARE ADVANTAGE RISK-ADJUSTED PAYMENTS

64. Unlike payments under Part A and Part B of Medicare, payments under Part C do not directly depend on the amount of healthcare services actually provided to an beneficiary. Under Medicare Part C, the Government pays each MAO a fixed, monthly capitated amount for each beneficiary enrolled in the MA Plan based on the expected average cost of care for that beneficiary. The payment is made on a per member, per month ("PMPM") basis and is adjusted for risk factors such as age, disability status, gender, and institutional status. The MA Plan's base rate is determined based on how the bid submitted by an MAO compares to an administratively set benchmark established under the Part C statute. *See* 42 U.S.C. § 1395w-23(a)(1)(B); 42 C.F.R. §§ 422.254, 425.304.

65. The plan's base payment rate is adjusted based on expected risk—or expected costs of healthcare—of each beneficiary. This adjustment is known as "risk adjustment."

66. Congress has required that the capitated payments be adjusted for each MA

Plan enrollee based on (1) each enrollee's demographic factors such as age and gender, among others, and (2) each enrollee's health status. *See* 42 U.S.C. § 1395w-23(a)(1)(C).

67. The risk score, which is sometimes referred to as the risk adjustment factor ("RAF"), is a multiplier that is applied to the MAO's base rate for covering the same services covered under Parts A and B. 42 U.S.C. § 1395w-23(a)(1)(G); 42 C.F.R. § 422.308(e).

68. The Secretary of HHS has the authority to determine the risk adjustment methodology. *See* 42 U.S.C. § 1395w-26(b). Since 2004, CMS has employed a hierarchical condition category ("HCC") model to calculate a risk score for each beneficiary in an MA Plan. As directed by Congress, the HCC model considers demographic factors and health status. *See id.* § 1395w-23(a)(1)(C)(i).

69. The HCCs are categories of clinically related medical diagnoses that include major, severe, and/or chronic illnesses. *See* 42 C.F.R. § 422.2. Each HCC is assigned an RAF that correlates with the predicted cost of care. Higher relative values are assigned to HCCs that include diagnoses with greater disease severity and treatment costs.[8]

70. Between 2004 and 2013, there were 70 HCCs in the Part C risk-adjustment model (known as Version 12). In 2014, CMS revised its risk-adjustment model (known as Version 22) and the number of HCCs increased to 79. HCC numerical codes also changed from the 2004-13 model to the 2014 model.[9]

71. With respect to health status, the HCC model relies on diagnosis codes documented by an authorized health care provider during a patient encounter—*e.g.*, during

[8] For example, under the current HCC model, a diagnosis of diabetes without complication would map to HCC 19, which has a RAF of 0.118, whereas a diagnosis of diabetes with acute complications would map to HCC 17, which has a RAF of 0.368.

[9] The numerical examples of HCC codes cited herein are from the Version 22 model.

office visits, hospital outpatient encounter, or inpatient stays.

72. HHS has adopted the International Classification of Diseases ("ICD") Guidelines for Coding and Reporting (the "ICD Guidelines") as the standard for medical record documentation, including the identification of diagnosis codes for health conditions. *See* 45 C.F.R. § 162.1002(a)(1)(i), (b)(1), (c)(2) and (c)(3) ("The Secretary [of HHS] adopts . . . the official ICD-10-CM Guidelines for coding and reporting"). CMS regulations, therefore, require MAOs to "submit data that conform to" the ICD Guidelines. 42 C.F.R. § 422.310(d)(1) (requiring MAOs to submit data in conformity with "all relevant national standards"); *see also* CMS, *Medicare Managed Care Manual* Chapter 7, Exhibit 30 (Rev. 57, Aug. 13, 2004).

73. ICD diagnosis codes are alphanumeric codes used by health care providers, insurance companies, and public health agencies to represent diagnoses. Every disease, injury, infection, and symptom has its own code.

74. The applicable standards for these ICD diagnosis codes are set forth in the International Classification of Diseases, Ninth Revision, Clinical Modification ("ICD-9") through October 1, 2015, and thereafter the International Classification of Diseases, Tenth Revision, Clinical Modification ("ICD-10").

75. To ensure accuracy, coded diagnoses must result from an encounter between a qualified health care provider and a patient during the DOS year and must be appropriately documented in the patient's medical record during the encounter.

76. According to both ICD-9 and ICD-10, which as mentioned above, are expressly adopted by CMS in 45 C.F.R. § 162.1002, MAOs should "[c]ode all documented conditions that coexist at the time of the encounter/visit, and require or affect patient care,

treatment or management." *See, e.g.*, ICD-9-CM Official Guidelines for Coding and Reporting (effective Oct. 1, 2011) ("FY11 ICD-9 Coding Guidelines") at 95, *available at* https://www.cdc.gov/nchs/data/icd/icd9cm_guidelines_2011.pdf; ICD-10-CM Official Guidelines for Coding and Reporting FY 2014 ("FY14 ICD-10 Coding Guidelines") at 104, *available at* https://www.cdc.gov/nchs/data/icd/icd10cm_guidelines_2014.pdf.[10]; *see also* CMS, *Medicare Managed Care Manual* Chapter 7, § 111.8 (Rev. 57, Aug. 13, 2004); CMS, *2008 Risk Adjustment Data Technical Assistance for Medicare Advantage Organizations Participant Guide* (2008).

77. The crux of this requirement is that a condition that is coded for risk adjustment must be supported—that is, the condition must be documented in the medical record as relevant to patient care during an encounter in the DOS year, and not merely mentioned, suggested, or inferred anywhere from records from past years. As the D.C. Circuit recently held, "Neither Congress nor CMS has ever treated an unsupported diagnosis for a beneficiary as valid grounds for payment to a Medicare Advantage insurer." *UnitedHealthcare Ins. Co.*, 2021 U.S. App. LEXIS 24141, at *1-2.

78. The 2004 Medicare Managed Care Manual states that "M+C organizations [now known as MA Organizations] must submit risk adjustment data that are substantiated by the physician or provider's full medical record." CMS, *Medicare Managed Care Manual*, Chapter 7, § 111.8 (August 13, 2004). The 2013 Medicare Managed Care Manual (the first revision since 2004) similarly states that MA Organizations "must . . . [e]nsure the accuracy and integrity of risk

[10] The quoted language is materially identical for all relevant versions of ICD-9 and ICD-10. Accordingly, unless stated otherwise, all references to the ICD refer to ICD-9 and ICD-10. All ICD Coding Guidelines for the relevant years are available at https://www.cdc.gov/nchs/icd/icd9cm.htm and https://www.cdc.gov/nchs/icd/icd10cm.htm.

adjustment data to CMS. All diagnosis codes submitted must be documented in the medical record . . . ." CMS, *Medicare Managed Care Manual*, Chapter 7, § 40 (June 2013).

79. Similarly, the 2003 Participant Guide stated that MA Organizations "must submit risk adjustment data that are substantiated by the patient's medical record." CMS, *2003 Regional Risk Adjustment Training for Medicare+Choice Organizations Participant Guide*, § 4.1.

80. Furthermore, the documentation requirement has been reiterated in multiple CMS training guides and materials since 2003. *See, e.g.*, CMS, *2008 Risk Adjustment Technical Assistance for Medicare Advantage Organizations Participant Guide* §§ 5.6, 6, 6.1, 6.4, 6.5, 7.1, 7.2; CMS, *2012 Regional Technical Assistance Participant Guide* § 2.2; CMS, *Risk Adjustment 101 Participant Guide* §§ 3.2.4; 4.3 (2013).

81. A beneficiary may have no HCCs, one HCC, or multiple HCCs. For example, a hypothetical Part C enrollee visits his physician and is diagnosed with depression, HIV, diabetes, and COPD. The physician (or typically a coder) will then submit a claim to the MAO for the services rendered, including these diagnoses. The MAO would render the claims and medical records from the encounter into the then-current ICD diagnostic codes for depression, HIV, diabetes, and COPD, and then submit these codes to CMS for possible risk adjustment. CMS would then convert the ICD codes to their corresponding HCC, if applicable.[11]

82. The HCC model is prospective, meaning that it relies on risk-adjusting diagnosis codes from the service year (the "DOS year") to determine payments in the

[11] In this hypothetical example, depression does not map to any HCC and, thus, no HCC will be assigned. Major depression, on the other hand, maps to HCC 59. HIV maps to HCC 1. Diabetes, depending on the severity, can map to HCC 17 (with acute complications), 18 (with chronic complications), or 19 (without complications). COPD maps to HCC 111.

following year, which is known as the "Payment Year" or "Plan Year." Each MA Plan beneficiary's risk score is calculated anew for the following year, based on documented conditions during the new DOS year.[12]

83. The mechanism for transmitting and submitting data is similar across the industry. After an encounter between a health care provider and a patient, the claims data are transmitted to the MAO, which either adopts the assigned ICD codes or renders the diagnoses in the medical records into their corresponding ICD codes. In turn, the MAO electronically submits these codes to CMS. CMS maps each beneficiary's risk-adjusting diagnosis codes to HCCs and calculates each beneficiary's risk score to determine the appropriate reimbursement to the MA Plan for that beneficiary for the following Payment Year.

84. Given the importance of accurate diagnosis coding to calculating the Government's payments, MAOs are required to ensure the accuracy of their data and submissions.

85. CMS audits MAOs and the MAOs audit providers to ensure the accuracy of their coding because of its importance to MA Plan reimbursement. *See UnitedHealthcare Ins. Co.*, 2021 U.S. App. LEXIS 24141, at *3 ("Payments to the Medicare Advantage program depend on participating insurers *accurately reporting* to CMS their beneficiaries' salient demographic information and *medically documented diagnosis codes*.") (emphasis added); *Silingo*, 904 F.3d at 673 ("The importance of [accuracy] . . . is obvious: if enrollee diagnoses are overstated, then the capitation payments to Medicare Advantage organizations will be improperly inflated.").

[12] Certain diagnosis codes trigger risk adjustment payment increases in both Parts C and D, so for certain of IH's enrollees, the false codes discussed herein will give rise to damages in both Medicare programs.

86. When false or erroneous risk-adjusting diagnoses codes are "swept" into the reimbursement system, CMS requires removal (or deletion) of the false or erroneous codes when the MAO learns of the error as well as the return of any overpayments. *See* Medicare Managed Care Manual, Chapter 7, §40 (June 2013); *Swoben,* 848 F.3d at 1176-77 & n.8 (9th Cir. 2016); *see also UnitedHealthcare Ins. Co.*, 2021 U.S. App. LEXIS 24141, at *1-2 ("Overpayment Rule requires that, if an insurer learns a diagnosis it submitted to CMS for payment lacks support in the beneficiary's medical record, the insurer must refund the payment within sixty days. The Rule couldn't be simpler.").

87. CMS also requires MAO executives to sign and, on behalf of the MAO, to "certify (based on best knowledge, information, and belief) that the [risk adjustment] data it submits . . . are accurate, complete, and truthful." 42 C.F.R. § 422.504(l)(2); *see also UnitedHealthCare*, 2021 U.S. App. LEXIS 24141, at *21 ("CMS's regulations have long obligated Medicare Advantage insurers to certify the accuracy of the data that they report to CMS" and, indeed, certification is "'a condition for receiving a monthly payment'"); *Silingo*, 904 F.3d at 673 (quoting certification requirement under 42 C.F.R. § 422.504(l)(2)). These certifications are a condition of payment by CMS. *See* 42 C.F.R. § 422.504(l)(3) (requiring related entities, contractors, and subcontractors of MAOs to certify the accuracy, completeness, and truthfulness of payment data they generate). *See, e.g.*, Exs. A at 8-9 (providing that CMS may terminate an MAO's contract for, among other reasons, failure to comply with applicable conditions and requirements under § 422 *et seq.*).

88. MAOs can delete diagnoses from both the Risk Adjustment Payment System ("RAPS") and Encounter Data System ("EDS") to comply with their obligation to delete known erroneous, invalid, false, or otherwise unsupported diagnosis codes previously

submitted to CMS.

89. Federal regulations and guidance make clear to MAOs and providers that CMS depends on accurate risk adjustment diagnosis coding to ensure appropriate reimbursement to MAOs. *See* 42 C.F.R. § 422.504(l)(3); CMS, *2013 National Technical Assistance Risk Adjustment 101 Participant Guide* 13 (2013) ("Accurate risk-adjusted payments rely on the diagnosis coding derived from the member's medical record."). In other words, MAOs and providers, including Defendants, have long been on notice that accurate diagnosis coding goes to the very essence of Medicare's bargain with and payment to MAOs.

IH'S RISK ADJUSTMENT PROGRAM

90. At all times relevant to this Complaint, Defendants knew the importance of risk adjustment and the workings of CMS's RAPS and EDS systems. Defendants were aware of (1) how the HCC model calculated a beneficiary's risk score; (2) regular changes to the HCC model; (3) the ICD classification system for diagnosis codes; (4) the mapping of risk-adjusting diagnosis codes to HCCs; (5) the importance of these risk-adjusting diagnosis codes in determining each beneficiary's risk score; (6) the direct relationship between a beneficiary's risk score and the ultimate payments to the MAO; (7) the requirements that each diagnosis code in a patient's records must result from an encounter between a qualified health care provider and the patient and be documented in the patient's medical records; (8) the importance of these requirements to payment under the MA Program; and (9) the duty to delete known invalid, false, or unsupported diagnosis codes and return overpayments to CMS.

91. Defendants were aware of their legal obligations under the MA Program. IH was also aware of its contractual obligations to CMS, and DxID was aware of its contractual

obligation to comply with all rules, regulations, and guidelines applicable to the MA Program.

92. Despite this knowledge, IH knowingly submitted risk-adjusting diagnosis codes for payments to CMS that were invalid, false, or unsupported by medical records or otherwise violated CMS rules, regulations, and/or guidelines that require that each diagnosis code submitted be the result of a documented condition that coexisted at the time of an encounter and required or affected patient care, treatment, or management in the relevant service year.

93. By submitting diagnosis codes that were not supported by medical records, IH also violated the terms and conditions of its contracts with CMS.

94. Defendants generated and knowingly submitted false claims through two methods: (1) retrospective chart reviews that violated CMS's requirements for coding conditions and (2) the improper use of addenda.

I. IH's Early Relationship with Gaffney.

95. IH's use of retrospective chart review and addenda began as early as 2007, starting with a company called Cognisight and its principals, Defendant Gaffney, Gregg Coughlin, and their consultant Dr. John Haughton. These individuals subsequently partnered with IH to form DxID and carry on the same fraudulent retrospective chart review services they had provided for IH at Cognisight.

96. Cognisight was formed in 2006 as a division of Greater Rochester Independent Practice Association ("GRIPA") in Rochester, New York.

97. Coughlin was the CEO of GRIPA. Coughlin hired Gaffney, and Gaffney introduced Haughton to Coughlin and GRIPA. GRIPA retained Haughton as a consultant.

98. Although neither Gaffney, Coughlin, nor Haughton was trained in risk adjustment, they formed Cognisight to provide retrospective chart review services for risk-

adjusted revenue.

99. Coughlin became the President of Cognisight.

100. Gaffney became Executive Vice-President at Cognisight.

101. Haughton served as a consultant to Cognisight and to GRIPA. Haughton entered an informal financial arrangement with Cognisight to receive an eight percent share of profits per year for consulting on risk adjustment related chart review services.

102. On October 8, 2007, Haughton contacted IH's President and CEO Michael Cropp seeking clients for Cognisight. In an email to Cropp, Haughton pitched Cognisight's ability to potentially "recover additional CMS $ for HCC optimization for the 2006 Calendar year, even though it is October 2007 now . . . ." He continued that the "HCC optimization process" "generated an additional $35 pmpm [per member per month] for the 2005 year across 15,000 patients under Medicare risk."[13] Haughton assured Cropp that Cognisight could analyze IH's data to determine whether it could recover additional CMS reimbursement free of charge to IH. According to Haughton, Cognisight was not proposing an HCC optimization process "to replace what [IH is] doing, but rather to enhance your existing process."

103. On November 2, 2007, Cognisight gave a presentation to IH's corporate executives regarding the risk adjustment strategies it could provide. Among those strategies was the use of addenda, which update or modify a medical record after a visit. As further explained below, while addenda are generally meant to allow providers an opportunity to make edits where there are technical or clerical errors on a medical record or to reflect new information that was not available at the time of the visit (*e.g.*, lab results), Cognisight used

[13] $35 per member per month over 15,000 members would result in additional revenue of $525,000 a month or $6.3 million for the year.

an "addenda process" to retroactively "capture" unsupported diagnoses by creating supporting documentation, often well after the provider-patient encounter.

104. Cognisight sent highly suggestive forms requesting that providers "fix" medicals records to add diagnoses that DxID asserted as coexisting during the patient encounter with the provider but were inexplicably omitted from the medical records.

105. As Cognisight explained to IH's executives during the November 2, 2007, presentation, Cognisight requested addenda up to a year after the encounter.

106. Cognisight's approach was driven by the financial returns. It touted the "expected return" from its services, telling IH executives that it could increase PMPM revenue by $15 million for 2006 using a *limited* addenda process, which would equate to $7 million in additional revenue to IH. Cognisight further guaranteed an additional $25 million PMPM increase for 2007 using the addenda process, which would equate to an additional $12 million per year in revenue.

107. According to Robert Tracy, IH's Senior Vice President of Government Programs, IH did not perform any due diligence to determine whether Cognisight, or its principals Coughlin, Gaffney, and Haughton, had the experience or ability to provide MA retrospective chart review services.

108. Nor did IH verify whether Cognisight's practices complied with CMS rules. At the time IH was considering hiring Cognisight, IH did not have a Medicare compliance department.

109. With respect to Cognisight's addenda process, Tracy explained that IH took no steps to determine if Cognisight's proposal to submit diagnoses based on addenda that were submitted up to a year after a patient encounter complied with CMS regulations or guidance.

Rather, IH accepted Cognisight's approach solely based on Cognisight's representations.

110. Without undertaking due diligence about Cognisight's experience, abilities, and compliance, IH hired Cognisight in 2007 to perform MA retrospective chart review services, which included an addenda process.

111. From the outset, IH employees who were involved in managing the MA Program recognized problems with Cognisight's risk adjustment practices. On December 4, 2007, an IH employee, Deborah Robinson, emailed Gino Startari, a Cognisight employee, and copied IH employees Michele Spagna and Tracy about instructions that they were receiving from Gaffney. Robinson reported that Gaffney was instructing coders "that if [a condition] was documented in the Problem list it could be reported." But Robinson noted that "[t]he CMS definition states that it must show evidence of evaluation & treatment in the note." Based on Robinson's experience, "the majority of records that we have reviewed over the past three years of auditing, the laundry list of chronic dx's are not evaluated/treated. Therefore, they would not be reported according to the CMS training guide."

112. This protest foreshadowed the controversies that would follow Cognisight, and later DxID when it succeeded Cognisight in providing retrospective chart review services to IH. Gaffney, first at Cognisight and later at DxID, pushed coding a "diagnosis" from "the laundry list of chronic" conditions that are listed on Problem Lists without regard for when the lists were created or whether the conditions listed required or affected patient care, treatment, or management during the DOS year.

113. Cognisight's use of addenda to create after the fact documentation was also a source of concern. In October 2008, a physician practice that contracted with IH to treat Part C beneficiaries, Buffalo Medical Group ("BMG"), questioned IH about its assertion that an

addendum could be submitted up to 12 months after the date of service. Although Tracy relayed BMG's concerns to Cognisight, the practice of submitting diagnoses based on old addenda continued.

114. Despite red flags, IH continued to contract with Cognisight for MA retrospective chart review services.

115. By 2011, IH received notice that Cognisight was submitting unsupported diagnoses for risk adjustment purposes. IH hired HealthRisk Partners ("HRP"), an independent risk adjustment consultant, in early 2011 to conduct an audit of Cognisight's risk adjustment practices. The audit raised serious concerns about Cognisight's coding practices.

116. In March 2011, Michael Faso, IH's Senior Vice President of Finance, sent a memorandum to Deloitte, an outside auditor, detailing issues that HRP had raised about Cognisight's practices that were causing high error rates in IH's risk adjustment program. Faso wrote:

> The mock RADV [("Risk Adjustment Data Validation")] audit of 50 members requires substantiation of 133 HCCs. While the audit is not yet complete, for the members with HCCs only coded through retrospective chart review (by an outside firm [*i.e.*, Cognisight]), HRP found nine of fourteen HCCs to be in error or otherwise unable to be substantiated in a RADV audit. . . . The preliminary conclusion reached by HRP indicates that there potentially are material abnormalities in the HCC data from retrospective chart review efforts of the plan versus coding results from other chart review vendors, or through the normal process of HCC coding.

Ex. F.

117. HRP's audit ultimately found errors in 68 percent of the charts Cognisight reviewed. According to HRP:

> The largest reason for failure (seven instances) was due to coding Chronic Kidney Disease (CKD) from lab

> values where the physician did not directly indicate this condition. Coding from lab values is not allowed by CMS or national coding standards. In these cases, HRP did not find any other instance of CKD before or after this coding from the lab value.

Ex. G.

118. HRP also provided IH with a chart entitled Coding Intensity by Vendor (with Renal Failure), which showed that Cognisight far exceeded a national vendor and HRP in coding diagnoses for kidney disease. Ex. H.

II. IH Creates DxID.

119. In or about December of 2010, Coughlin and Gaffney were terminated by GRIPA. Haughton's consulting role was also terminated.

120. After learning that they had been terminated by GRIPA, and despite being aware of concerns and red flags about their unsupported coding practices at Cognisight, Faso advised IH CEO Cropp and the IH Board of Directors to hire Gaffney and Coughlin to form a new chart review entity that would capture codes for risk adjustment revenue.

121. IH hired Gaffney and Coughlin to create a new chart review vendor in the summer of 2011. The new entity, called DxID, would be a subsidiary of IHC, the for-profit arm of IH's business.

122. Haughton would again serve in an advisory and consulting capacity to the newly formed DxID. He was listed as DxID's Chief Innovation Officer on the company's website from July 2011 through about January 2018. Haughton would also become an IH employee in or about 2016, serving as a part-time Chief Innovation Quality Officer until 2018 when he was hired full-time to work on Medicare, risk adjustment, and chart review projects.

123. Gaffney, Coughlin, and Haughton implemented the same fraudulent risk

adjustment coding practices for DxID that they had implemented at Cognisight.

124. Although IH had been repeatedly warned about these practices and, in 2013, had to refund nearly $700,000 to CMS for some of the same practices, IH nevertheless used DxID as its chart review vendor for submitting newly captured codes to CMS for risk adjustment revenue for DOS years 2010 through at least 2017.

125. On information and belief, IH continued to use DxID until DxID ceased operating in or about August of 2021.

III. Defendants Conspired to Commit Fraud.

126. From no later than August 31, 2011, IH created DxID as a wholly-owned subsidiary and appointed Gaffney as its CEO[14] to provide retrospective chart review and addenda services.

127. IH, DxID, and Gaffney conspired to violate the FCA by agreeing to code diagnoses that were not documented in medical records during patient visits or encounters or that otherwise did not meet CMS rules and regulations for risk adjustment coding.

128. As overt acts in furtherance of their conspiracy, Gaffney and DxID coded diagnoses that were not documented in medical records and transmitted the codes to IH for submission to CMS, IH did submit the codes to CMS for risk-adjusted payments, and IH remitted a contingency fee based on its recovery to DxID.

[14] Gaffney was originally co-CEO with Coughlin. She later became sole CEO.

THE SCHEME TO DEFRAUD

I. Defendants' False Claims.

129. Defendants knowingly submitted false claims, or caused false claims to be submitted, and knowingly retained payments from Medicare based on a systematic process to capture and code diagnoses that did not meet CMS rules for MA risk adjustment coding. Defendants principally relied on two methods to capture unsupported diagnosis codes: (1) retrospective chart review program that violated CMS's requirements for coding for risk adjustment and (2) the use of improper addenda.

130. DxID carried over these fraudulent policies and practices that Gaffney developed and used at Cognisight to capture unsupported diagnosis codes for its clients, including IH and GHC.

131. On behalf of GHC, Defendants DxID and Gaffney implemented policies and practices that ran afoul of CMS rules, regulations, and guidance, as well as IH's obligations under contracts with CMS, in connection with the retrospective chart review program, which resulted in the submission of diagnosis codes that were not adequately documented as relevant to patient care during an encounter in the DOS year. Specifically, GHC adopted DxID's fraudulent retrospective chart review program for DOS years 2010 through 2011. GHC, however, declined to adopt DxID's misuse of addenda.

132. DxID's fraudulent retrospective chart review program caused GHC to submit 4,946 new diagnosis codes to CMS in January 2012 for DOS year 2010, which resulted in $12,341,186.81 in new revenue to GHC from CMS. Pursuant to its contract with DxID, GHC paid DxID 20 percent of its additional revenue or $2,468,237.76.

133. GHC again relied on DxID for retrospective chart review services for DOS year 2011. DxID's services resulted in $20,368,458.65 in additional payments from CMS to GHC. Accordingly, GHC paid DxID 20 percent of that amount or $4,073.691.73.

134. IH contracted with DxID and Gaffney to implement their fraudulent retrospective chart review program and complemented it with the addenda process for DOS years 2010 through at least 2017, which resulted in the submission of diagnosis codes that were not adequately documented as relevant to patient care during an encounter in the DOS year. As a result of DxID's fraudulent retrospective chart review services, IH submitted hundreds of thousands of new diagnosis codes—including over 125,000 from the addenda process alone—that resulted in CMS paying IH tens of millions of dollars.

II. DxID's Fraudulent Retrospective Chart Review Program.

135. A retrospective chart review program is a process by which an MA plan or a vendor, such as DxID, re-reviews its Part C enrollees' medical records to confirm that coded diagnoses are supported by the medical records, to identify unsupported diagnoses and submit the codes for withdrawal or deletion, and to capture conditions that are supported by medical records but have not been coded.

136. Retrospective chart reviews are sometimes the third or fourth coding review, after an MAO's initial coding, secondary sweeps, and other tertiary chart reviews for risk adjustment coding purposes.

137. As discussed above, DxID captures and MAOs like IH submit additional diagnoses codes to CMS, which increase risk adjustment scores and capitation rate. "[I]f enrollee diagnoses are overstated, then the capitation payments to Medicare Advantage organizations will be improperly inflated." *See Silingo*, 904 F.3d at 673.

138. The financial incentives to over-code are self-evident. *See id.* at 672 ("human nature being what it is, Medicare Advantage organizations also have some incentive to improperly inflate their enrollees' capitation rates, if these organizations fall prey to greed."). As such, all diagnosis codes submitted must be properly supported by the medical records.

139. According to ICD Guidelines, which are incorporated into federal regulations, *see* 45 C.F.R. § 162.1002(c)(2) and (c)(3), MA plans are instructed to "[c]ode all documented conditions that coexist at the time of the encounter/visit, and require or affect patient care, treatment or management." *See, e.g.*, FY14 ICD-10 Coding Guidelines at 104; FY11 ICD-9 Coding Guidelines at 95.

140. In incorporating these guidelines, CMS requires that all diagnoses that are submitted for risk adjustment be based on encounters with a qualified provider during the date of service year and supported by documentation in the medical records.

141. With its retrospective chart review program, however, DxID knowingly violated the rules and captured diagnosis codes that were not documented by a qualified provider, that did not exist at the time of the encounter or visit, that did not require or affect patient care, treatment, or management, and/or that were otherwise unsupported by the medical records. These codes should not have been submitted to CMS.

142. DxID's fraudulent chart review program relied on "trolling" patient medical records to gin up, in many cases, "new" diagnoses exclusively from information derived from impermissible sources like Problem Lists, Past Medical History, labs (e.g., diagnostic and radiology tests), and orders for Durable Medical Equipment ("DME"), such as oxygen.

143. DxID's fraudulent chart review program policies were memorialized in its internal coding document known as the DxID Global Coding Policy ("GCP"). Ex. I.

144. The GCP instructed DxID coders that "Continuing Chronic conditions, defined by the DxID Clinical Team, documented in the assessment of a face-to-face encounter will be coded." Ex. I at 6. This guidance is unremarkable. Indeed, an MAO would likely have identified such diagnosis codes in its initial review or during a secondary review or audit of claim files or medical records. DxID's value, therefore, was its ability to "capture" diagnosis codes that were purportedly overlooked in the MAO's normal risk adjustment coding, and it often accomplished this by capturing diagnoses that were not allowed by CMS rules, regulations, guidelines, and contracts for MA Programs.

145. For example, although CMS requires data to comply with "all relevant national standards," 42 C.F.R. § 422.310(d), which includes the ICD requirements that do not allow for risk adjustment for conditions that do not "require or affect patient care, treatment or management" in the service year, the GCP erroneously directed DxID coders to submit diagnosis codes for conditions that appear in separate sections of medical records that are unrelated to any patient care, treatment, or management during an encounter in the relevant DOS year.

146. The GCP specifically directed coders to code from Problem Lists regardless of whether the condition listed on the Problem List was documented by a provider as relevant to patient care during an encounter in the DOS year.

147. Problem Lists are used within health records to list illnesses, injuries, conditions, and other factors that *could* affect the health of an individual patient. The list can include old or prior conditions, new conditions based on current symptoms or drugs taken, predicted conditions based on prescription drugs or health status, or suggested conditions from computer algorithms, among others. Problem Lists are often auto-generated or auto-

populated. Without documentation indicating that the condition was a factor during a patient encounter or visit during a relevant service date, coders cannot discern what, if any, conditions listed on the Problem List in fact required or affected patient care, treatment, or management.

148. Depending on the electronic medical record system that a provider uses, a Problem List for a hypothetical patient who is taking prescription opioid for pain management and uses an inhaler for asthma may include possible risk of opioid dependence and COPD. Although diagnoses related to opioid dependence or COPD are conditions that map to HCCs and risk adjust, the hypothetical patient may have neither. Thus, a condition listed on a Problem List is not an *actual* diagnosis.

149. But according to DxID's GCP, "Continuing chronic conditions, defined by the DxID Clinical Team, documented on a signed and dated problem list will be coded." Ex. I at 11. This direction is without regard for the condition's origin on the Problem List, the process for adding conditions to the Problem List, whether the original provider ever used the Problem List, and whether the service year provider saw, let alone consulted, the Problem List.

150. Although DxID recognized that "providers used problem lists inconsistently," which showed an awareness of why CMS prohibits relying on Problem Lists to code serious or chronic conditions for risk adjustment, the GCP further instructed that "Chronic conditions on a signed and dated problem list without contradictory information should be considered co-existing conditions." Ex. I at 9.

151. In fact, the GCP expressly instructed coders to disregard the absence of "medical intervention" for conditions to be coded from a Problem List. According to the GCP: "Chronic conditions *that may resolve*, as defined by the DxID Clinical Team, listed on

a signed and dated *problem list*, embedded in an encounter note of a face-to-face encounter *will be coded in the absence of medical intervention*." Ex. I at 14 (emphasis added).

152. As such, under the GCP, DxID disregarded ICD Guidelines to code only "documented conditions that coexist at the time of an encounter/visit," where the conditions "require or affect patient care, treatment or management" during the service year by a qualified provider.

153. As explained further below, the GCP's guidance was put into practice at IH and at GHC, which both submitted codes that DxID captured from Problem Lists without any other evidence that the conditions were documented in the medical record as relevant to patient care during an encounter in the DOS year.

154. As with Problem Lists, DxID also coded from Past Medical History without regard for whether the condition was documented by a provider as relevant to patient care during an encounter in the DOS year. The GCP instructed that "Continuing Chronic conditions, defined by the DxID Clinical Team, that are documented as 'history of' will be coded. Continuing Chronic diagnoses listed in the 'Past Medical History' will be coded." Ex. I at 14.

155. This instruction directly conflicts with the ICD Guidelines' requirement that "history (categories V10-V19) may be used as secondary codes *if the historical condition or family history has an impact on current care or influences treatment*." *See, e.g.*, FY11 ICD-9 Coding Guidelines at 95 (emphasis added).

156. DxID's erroneous approach to coding from Past Medical History is exemplified by its coding for old myocardial infarction ("Old MI"), which refers to an old heart attack, from Past Medical History. A DxID document titled "Medicare Advantage

Documentation & Coding Tips" instructed that "[i]t is important to capture [an Old MI] diagnosis whenever it occurs."

157. This policy is violates Part C coding rules. While Old MI can be relevant to present care, it should not be coded for risk adjustment unless it is documented in the medical record as relevant to patient care during an encounter in the DOS year. Neither the ICD nor CMS permits coding conditions simply because they existed in the past.

158. Nevertheless, DxID often captured "Old MI" diagnosis codes, and IH and GHC submitted those codes, based solely on a note in Past Medical History stating that a patient had a heart attack several years earlier, or even more than a decade prior to an encounter in the DOS year.

159. Similarly, the GCP instructed coders that "Chronic conditions, such as, but not limited to, hypertension, Parkinson's disease, COPD, and diabetes mellitus are chronic systemic diseases that ordinarily should be coded even *in the absence of documented intervention or further evaluation*." Ex. I at 4 (emphasis added).

160. This policy directly contradicts the ICD Guidelines, as adopted by CMS, to "[c]ode all documented conditions that coexist at the time of the encounter/visit, and require or affect patient care, treatment or management."

161. The GCP also impermissibly instructed coders to code directly from lab results or device orders, in contravention of CMS rules, regulations, and guidelines.

162. For example, DxID instructed coders to code Old MI based solely on the indication from an electrocardiogram ("EKG"). DxID's "Diagnosis Specific Chronic Condition Coding Policy," which "supplements the DxID global coding policy for specific diagnoses," contains the instruction and rationale for coding Old MI from EKGs. Ex. J at 1.

After acknowledging that it is "DxID's policy to code all old myocardial infarctions documented on signed and dated progress notes," the policy further instructs: "electrocardiograms can be used to support the presence of an old myocardial infarction." *Id.* at 2.

163. In support of this instruction, DxID cited a CMS FAQ that states, "[A]n EKG report with the diagnosis *documented on the report* and *a physician signature* is acceptable documentation to code a diagnosis of 412 (old myocardial infarction)." Ex. J at 2 (emphasis added). However, DxID omitted key parts of CMS's guidance which states that the diagnosis must be "documented on the report" and supported by "a physician signature." DxID asserted instead that CMS's guidance "establish that EKG reports are, in many cases, acceptable to code an old myocardial infarction." *Id.* at 2.

164. As discussed further below, DxID captured, and IH and GHC submitted, diagnosis codes for Old MI supported only by EKGs.

165. DxID also instructed coders to code chronic kidney disease ("CKD") from lab reports alone. Although Gaffney acknowledged that coding CKD could be risky and that "lab values as the ONLY evidence of the disease, would not pass RADV," she claimed that "labs being available at the time of a face to face allows assumption" that CKD was considered and therefore it would be acceptable to submit CKD diagnosis codes. In other words, DxID would *infer* that a report was relevant to the patient's care from the mere fact that the report was available during an encounter, even without any documentation suggesting that the provider looked at the report.

166. Despite acknowledging that coding from labs was impermissible, Gaffney falsely told IH that "CMS indicates that they expect labs to be coded."

167. As discussed further below, DxID often captured, and IH and GHC submitted, CKD codes based solely on labs without any other evidence that CKD was documented by the provider as relevant to patient care during an encounter in the DOS year.

168. DxID also instructed its coders to code hypoxemia based on DME orders for oxygen. According to DxID's "Medicare Advantage Documentation & Coding Tips," coders should "[d]ocument Hypoxemia when . . . the patient is prescribed continuous oxygen and has a qualifying condition (COPD, Cor Pulmonale, CHF, etc.)." Ex. K at 28.

169. Gaffney explained in an email of October 25, 2012, that "An order for/use of continuous O2," using the shorthand for oxygen, was sufficient "for DxID to identify Hypoxemia as a code able [sic] diagnosis."

170. This advice was inconsistent with CMS's rules and guidelines. The presence of an order for oxygen, even combined with other conditions, is not sufficient to establish hypoxemia for risk adjustment purposes. Rather, the medical record must indicate hypoxemia or that the patient suffered from oxygen levels low enough to infer hypoxemia.

171. Nevertheless, as discussed further below, DxID captured, and IH and GHC submitted, hypoxemia codes based on a patient's use of oxygen alone.

III. DxID and Gaffney Caused GHC to Submit False Claims.

A. GHC hired DxID based on IH's recommendation and DxID's promises of financial gain.

172. GHC historically managed chart reviews and risk adjustment for its MA Plans internally.

173. GHC's Documentation and Coding Core Team ("DCC Team") was responsible for making policy decisions related to MA risk adjustment.

174. GHC also had a Chronic Condition Review Team ("CCR Team"), which was governed by the DCC Team. The CCR Team was led by Dr. Donald Rappe and Relator, Teresa Ross.

175. In 2011, GHC was exploring the use of a vendor for chart reviews to augment its risk adjustment coding, beyond what the CCR Team was able to secure.

176. In or about September 2011, IH CEO Cropp and GHC President and CEO Scott Armstrong began discussing their common concern regarding Medicare margins. Cropp told Armstrong that IH "picked up the key assets of a company called Cognisight that had carved out a nice niche in the HCC revenue recovery space. Betsy Gaffney, the woman who founded Cognisight[,] is now working for a company we started called DxID that is essentially doing what Cognisight did for us . . . ."

177. Gaffney subsequently followed up with Armstrong and other GHC employees tasked with vetting risk adjustment vendors on October 5, 2011. Gaffney boasted that "[t]he processes and technologies that we have developed have resulted in annual recoveries of $60 PMPM (yes, actually that is the amount) annually for the past four years. Our recovery averages have been between $35 PMPM up to $84 PMPM for similar plans." She further explained that DxID operated on a contingency basis, stating: "There is no upfront fee, we don't get paid until you get paid and we work on a percentage of the actual proven recoveries."

178. Gaffney's pitch contained two themes that she would emphasize throughout her dealings with GHC. First, she would emphasize the financial gains of DxID's approach, suggesting or often stating outright that the financial gains were too attractive to pass up. Second, Gaffney would tell GHC that her approach had the backings of several MAOs, giving

the impression that it was not doing something outside of the norm, although Gaffney would not (or could not) identify any other MAO using DxID's coding approaches besides IH.

179. On November 1, 2011, Gaffney met with members of GHC's DCC Team to sell DxID's services. She followed up by email on November 3, 2011, urging GHC to move quickly in hiring DxID so that it could review DOS year 2010 charts by January 31, 2012—the deadline for submitting diagnoses for DOS year 2010 to CMS.

180. Gaffney's and DxID's pitch to GHC raised red flags within GHC from the outset. But Gaffney pushed back, arguing that GHC was being too conservative in its risk adjustment program. She argued to Debbie Sather, GHC's Executive Director of Finance Administration, that GHC's coders were "applying very strict policy rules to a CMS requirement, where there is no CMS requirement to do that."

181. In further correspondence with Sather on November 23, 2011, Gaffney continued to fault GHC for being overly conservative, while misrepresenting CMS guidance and emphasizing the financial benefits of DxID's approach. She explained: "The way you are enforcing the submissions at this point is really putting you back financially. I get what the purpose of the policies are theoretically, and even kind of agree philosophically, but it is very restrictive and has nothing at all [t]o do with CMS or ICD 9 coding rules."

182. Gaffney ultimately prevailed on GHC, and GHC awarded DxID a two-year contract for retrospective chart review services on December 14, 2011. *See* Ex. E.

183. The contract between GHC and DxID provided a clear financial incentive for DxID to over-code diagnoses for GHC's risk adjustment submissions by specifying that DxID was entitled to receive "20% of Actual Net HCC Recoveries" from DxID's retrospective chart

review program for DOS years 2010 and 2011, which corresponded with payment years 2011 and 2012, respectively. *See* Ex. E at 13.

B. DxID and Gaffney recommended that GHC submit unsupported diagnosis codes based on DxID policies.

i. DxID recommended coding various conditions from Problem Lists and Past Medical History.

184. Relying on DxID's retrospective chart review policies described above, Gaffney convinced GHC to capture diagnoses from Problem Lists even where there was no documentation in the medical record that the condition was relevant to patient care during an encounter in the DOS year.

185. To accomplish this, Gaffney provided several rationales in an attempt to obfuscate the fraudulent practice of coding from Problem Lists alone.

186. Gaffney sent GHC a document titled "DxID Considerations for Medical Record Review and Diagnosis Collection," which stated: "Since the active problem list is within the encounter note under the section entitled 'Evaluation' it seems to meet the requirement" for coding the diagnoses.

187. Ordinarily, the qualifiers—"active problem list" that "is within the encounter note" and is "under the section entitled 'Evaluation'"—did not satisfy CMS's documentation requirement. In any event, they did not reflect DxID's actual practice of coding from Problem Lists alone and without any of these qualifications being in place.

188. Based on DxID's recommendations, GHC submitted diagnosis codes for risk adjustment solely based on a condition's presence on a Problem List, including in instances when the medical record indicated that the condition was not present.

189. For example, DxID coded, and GHC submitted, "Major depressive disorder, single episode, unspecified (296.20)" for Patient RB, "a 87 year old male," in DOS year 2010 based on a Problem List and despite conflicting information on the "Progress Notes." Progress Notes are typically current statements of the conditions assessed during an encounter, while Problem Lists are a laundry list of current, historical, or predicted conditions.

190. For this patient, the Problem List included 21 conditions, including major depressive disorder, but the Progress Notes of the September 2010 encounter indicated that the provider assessed up to five conditions. Notably, the physician's assessment that is documented in the Progress Notes states, "Depression resolved. Transient related to time of his sister's death. Had asked to go off SSRI earlier this year when was feeling better and still feels good." In another section of the medical record, containing "Assessment/Plan," the physician noted, "Depression - situational, resolved."

191. Major depression is a severe condition that maps to an HCC and risk adjusts. Depression is a serious but lesser condition that does not risk adjust. In any event, there is no indication that this patient was assessed for major depression during the 2010 DOS year, except for notation on the Problem List that the patient may have had major depression at some time in the past. And even though the same record indicates that the depression was resolved, DxID coded it without resolving any potential conflict, and GHC submitted the code for risk adjustment.

192. DxID also captured a diagnosis code for "pancreatitis 3-09 (577)" for Patient EP in DOS year 2010 based on the presence of pancreatitis on a Problem List containing 12 conditions. DxID captured this diagnosis code based on an encounter in November 2010 with

an ophthalmologist, where the patient was assessed for glaucoma, macular degeneration, and cataract. There is no documentation suggesting, let alone showing, that pancreatitis was a factor in the eye exam. Indeed, the medical record indicated that the pancreatitis was entered by another physician in 2009. Nevertheless, GHC submitted the diagnosis code for 2010 DOS year.

193. Similarly, DxID coded uncontrolled diabetes (250.92A) for Patient RC based on a reference in a Problem List containing about 12 conditions during a November 9, 2010, dermatology appointment for skin lesion and bump behind Patient RC's left ear. Despite lack of documentation that diabetes was a factor in the dermatologist encounter, DxID coded the condition based on that encounter and GHC submitted the code to CMS for risk adjustment.

ii. DxID recommended GHC capture other diagnosis codes in violation of coding rules, regulations, and guidance.

194. DxID also recommended that GHC submit other diagnosis codes for risk adjustment, including but not limited to Old MI, CKD, and hypoxia/hypoxemia in violation of the ICD Guidelines, which are incorporated by CMS.

195. DxID and GHC specifically discussed DxID's approach to coding Old MI, hypoxemia, and CKD on multiple occasions, including during a December 30, 2011, conference call,[15] which was captured in notes prepared by DxID.

1. Coding Old MI from EKGs.

196. Gaffney and DxID advised GHC to submit diagnoses that were only supported by diagnostic tests, such as EKGs. For example, DxID advised that GHC could "consider

[15] Gaffney, Dario Delkic (Senior Manager, Client Services), Paul Starowicz (Clinical Manager), and Jane Dean (Clinical Coder) attended for DxID. Sather, Rhona Moses (Director of Health Information Management), and Stephen Tarnoff (Associate Medical Director) attended for GHC.

using . . . [EKG] as clinical support to code old myocardial infarctions." This advice was not consistent with coding rules, regulations, and guidelines.

197. During the December 30, 2011, conference call, the participants recognized that "Old MI is frequent [in GHC patient population] and generally not specifically documented, but always relevant to care." The fact that it is "not specifically documented" means that the condition should not be coded for risk adjustment.

198. Despite the admission that the condition is "not specifically documented," Gaffney and DxID falsely recommended that "Coding rules . . . around Old MI are that you should always code if it ever occurred." Disregarding the requirement for documentation during the qualifying encounter, Gaffney told the meeting participants that "[d]octors usually do not document Old MI, they document the heart attack. From a coding rule standpoint, you should always code old MI, apply the CMS medical record documentation rules that it is easily inferred from the medical record. . . ." *Id.* In other words, Gaffney's position was that the presence of a confirmed heart attack based on an EKG result from a prior year allowed DxID to capture Old MI, regardless of when the EKG occurred and including when Old MI was not documented in the medical record as requiring or affecting patient care, treatment, or management during an encounter in the DOS year.

199. On January 11, 2012, nearly two weeks after the conference call, Gaffney sent an email to Sather with the subject line "Okay - Old MI again . . .," in which she confirmed that DxID would code Old MIs from EKGs only. Gaffney explained, again ignoring binding rules and contractual obligations, that "when an Old MI is targeted, they look on the active problem list - then they check the EKGs and verify that it was confirmed. Then we allow the OLD MI to be pushed to RAPS in QA for GHC."

200. DxID's process for coding Old MI from EKGs from years before the DOS year was further confirmed in the attachment to the January 11 email to Sather, which contained six explanatory examples of instances where DxID would capture an Old MI condition from EKGs only, and one example where it would not.

a. In Example 1, a patient sees an optometrist, with "Patient Active Problem List within an Encounter Note" indicating "'h/o Perioperative MI (412)." The optometrist signed the encounter note. Here, Gaffney said DxID "would not take this one," meaning it would not capture the Old MI, because the provider was an optometrist and the optometrist "may not have reviewed this diagnosis to support the treatment he might be providing."

b. In Example 2, "Confirmed EKG" in 2009 reflected infarctions in 2008 and 2006. According to Gaffney, DxID "would take this one" because "[t]he confirmed EKG is available to the physician at the time of an encounter. All the coding rules we can find indicate that the confirmed diagnosis of Old MI is codeable."

c. The remaining five examples all involved EKGs obtained before 2010 (the DOS year). Gaffney stated that DxID "would take" all based on EKGs alone and a summary declaration by DxID that "[t]he confirmed EKG is available to the physician at the time of an encounter."

201. DxID's decision to code an Old MI diagnosis based on EKGs alone was not consistent with CMS's rules for only coding conditions that are documented in the medical record as relevant to patient care during an encounter in the DOS year. But given the purported frequency of undocumented Old MI among GHC's members, this coding practice

was lucrative. During the time that Gaffney and DxID were recommending that GHC submit Old MI diagnoses from EKGs, Old MI would have mapped to HCC 83 and was assigned a corresponding community risk adjustment factor of 0.244, resulting in GHC receiving at least 124.4 percent in PMPM payment and possibly other increases for disease interactions.[16] Pursuant to its contract with GHC, DxID would receive 20 percent of the incremental proceeds that CMS paid to GHC.

202. In fact, Gaffney explicitly relied on the substantial value of Old MI to make the case to GHC to accept the Old MI diagnosis codes. In her January 11, 2012, email to Sather, Gaffney explained that ".244 is factor for Old MI" and "[l]ets [sic] assume that within the 17K charts, there are 1,500 valid Old MI's – we are getting to some pretty big numbers," specifically $2.6 million. She declared the approach as "fully valid and fully defendable" and that "there is no risk in taking them, in fact - pretty much this is all there ever is to document them held in any medical record."

203. GHC agreed to submit diagnosis codes for Old MIs from EKGs. As Sather wrote to Gaffney on January 12, 2012, "for 2010 please treat them like you would for other plans."

2. Coding hypoxemia from the presence of oxygen.

204. Gaffney and DxID also advised GHC to capture diagnoses from the order or use of durable medical equipment (or DME). Most commonly, Gaffney recommended coding hypoxia or hypoxemia (low level of oxygen in the blood) solely from the home use or order of oxygen.

[16] This calculation is rudimentary and does not account for other risk factors that may apply to this hypothetical enrollee, including risk adjustments for demographic factors and other chronic conditions that are properly coded.

205. This contradicts coding rules and guidelines against coding conditions from DME generally, as well as the ICD requirements for documentation that a condition exists in the DOS year.

206. DxID, however, did not require documentation that a patient had a low level of oxygen or that the low level was assessed in any way during an encounter in the DOS year. Rather, DxID captured hypoxemia based solely on an indication that the patient was given oxygen to use at home in past years. To Gaffney, an MAO could infer and code hypoxemia from that information.

207. Gaffney provided multiple justifications to support DxID's coding policy and practice, including relying on guidance for fee for service coding that was irrelevant to risk adjustment coding.

208. Gaffney also relied on the notion that oxygen is used to treat hypoxemia. While this is generally correct, the existence of an oxygen order or use at home, without more, does not provide adequate justification for, or create an inevitable inference of, hypoxemia.

209. Gaffney frequently relied on the financial incentives to support her position. In an email to Sather on December 22, 2011, Gaffney criticized GHC's prior coding rules that required hypoxemia to be "written in a note" on the medical record to code it, while accusing GHC of leaving money on the table that other plans were recouping. As Gaffney explained, GHC was "not receiving the risk adjustment payment for [hypoxemia]—where other plans are."

210. On a conference call held about a week later, on December 30, 2011, Gaffney stated: "Typically DxID would code hypoxemia if COPD is listed in active problem list and

member is on oxygen. We would say that the doctor has recognized Hypoxemia and ordered the oxygen."

211. This time, Gaffney was relying on the presence of a secondary condition, COPD, that, as a matter of coding rules, was immaterial to the proper documentation of hypoxemia during the encounter in the DOS year. While COPD and hypoxemia can coexist, the existence of one does not provide documentation for the other.

212. Ultimately, DxID's policy and practices promoted coding hypoxemia based on oxygen order or use alone, regardless of a documented secondary respiratory condition, in violation of the ICD and CMS coding regulations, rules, and guidelines.

213. During this time, hypoxemia would have mapped to HCC 79, which was assigned a corresponding community risk adjustment factor of 0.578, resulting in GHC receiving at least 157.8 percent in PMPM payment, plus any additional increase for disease interactions. DxID again would receive 20 percent of the incremental proceeds that CMS paid to GHC.

3. Coding kidney disease from lab results.

214. Gaffney and DxID fraudulently caused GHC to code CKD from lab results.

215. During the December 30, 2011, conference call with GHC, Gaffney recommended that GHC code CKD "at only stages 3 and above where lab values over time, that were available to the treating physician at the time of a visit would be indicative of the treatment and care of the condition."

216. This is, however, a leap that is not permitted under CMS rules or under Defendants' contractual obligations. The existence of lab values (typically from previous years and from other providers) and the encounter in the DOS year are separate events that, without

evidence, cannot be presumed to converge. The absence of documentation in the medical record that old lab values were relevant to patient care during an encounter in the DOS year renders the old lab values inadequate for coding for risk adjustment purposes.

217. During this time, CKD would have mapped to HCC 131 and assigned a corresponding community risk adjustment factor of 0.368, resulting in GHC receiving at least 136.8 percent in PMPM payment, plus any additional increase for disease interactions.[17] DxID would have received 20 percent of the proceeds.

4. Coding atherosclerosis from incidental findings.

218. Gaffney and DxID advised GHC to code atherosclerosis from Incidental Findings.

219. Incidental Findings are undiagnosed conditions that are *incidentally* shown on test results (e.g., lab tests, chest x-ray, etc.) that were ordered for other purposes.

220. On January 27, 2012, a few days before the submission to CMS for DOS year 2010 were due, Rhona Moses, GHC's Director of Health Information Management, asked Gaffney whether DxID was taking the position that "a link within the encounter note to a Rad[iology] report that includes an incidental finding of 'atherosclerosis' to be sufficient to code atherosclerosis when there is no mention of that diagnosis in the encounter note (or any other encounter note in the reporting year)?"

221. Although Gaffney initially responded that that was not her position, she firmly embraced the position, explaining that "[w]hen the radiology report is available at the time of

[17] During this period, CMS recognized a disease interaction between CKD and congestive heart failure ("CHF") as INT5, which was assigned a community risk adjustment factor of 0.231. So when DxID coded CKD and the enrollee was also assigned the diagnosis code for CHF, the risk score will include CKD (0.368), CHF (0.410), and INT5 (0.231), among other conditions that the enrollee has.

the treatment, I do believe that you can support the code in a physician record . . . .” Gaffney went on to state that there is “no question, the report being available to the physician at the time of a face to face will allow the code. Medicare makes the assumption that if it is available to the doc, then you can assume he reviewed it.”

222. Gaffney’s logic rests on multiple incorrect assumptions and a misstatement of CMS rules and Defendants’ contractual obligations. First, she assumed that the existence of medical records from past years, such as a radiology report, means that the records were available to the provider during a service year encounter. Second, she misstated Medicare rules, falsely stating on multiple occasions that “Medicare makes the assumption that if it is available to the doc, then you can assume he reviewed it.” And if a record, which is assumed to be available to a provider, who is assumed to have reviewed it, contains an Incidental Finding, it can similarly be assumed that the provider reviewed, assessed, and confirmed the incidental condition as well.

223. These faulty assumptions led Gaffney to do precisely what she falsely claimed DxID did not do, which was to code atherosclerosis from Incidental Findings. GHC submitted the codes for risk adjustment revenue.

224. Around that time, atherosclerosis would have mapped to HCC 105, which was assigned a community risk adjustment factor of 0.316, resulting in GHC receiving at least 131.6 percent in PMPM payment, plus any additional increase for disease interactions. DxID would have received 20 percent of the proceeds.

C. GHC expressed concerns about DxID's approach.

225. Before submitting DxID's newly captured codes for DOS year 2010 to CMS, GHC conducted an audit of DxID's retrospective chart review work and discovered several instances of coding unsupported diagnoses.

226. By January 25, 2012, Moses had reviewed a sample of 20 diagnoses found through DxID's retrospective chart review. The purpose of the review was to verify that DxID was following agreed upon guidelines. Moses, however, concluded that "there are several cases that I need to bring to someone's attention."

227. One of the diagnosis codes DxID captured was for atherosclerosis based on "an incidental finding in a results summary of an x-ray report; it is not signed or addressed in any way by the FP provider."

228. At least 10 of the audited 20 conditions that DxID captured were "only mentioned in the auto-populated problem list." One example is particularly illustrative. DxID captured and reported a diagnosis code related to diabetes with ophthalmic manifestation from an auto-populated Problem List. According to the GHC's audit, this condition was "only mentioned in the auto-populated problem list along with 29 other diagnoses." The audit further noted that "CMS has stated that P[roblem]L[ist]s are not acceptable documentation unless updated/annotated . . . ." *Id.*

229. Two of the 20 audited conditions were captured from an old Problem List. In one instance, DxID captured atrial fibrillation based on "condition [that was] documented in the Problem List with a comment that was entered by the provider in 2005 and has not been updated since." In another instance, DxID captured hypoxemia based on a "condition [that

was] documented in the Problem List with a comment that was updated by the provider in 2009 and has not been updated since." *Id.*

230. Two of the 20 audited conditions were captured from Past Medical History. For example, DxID captured a diagnosis of alcohol dependence from "a non-updated entry from 2007." According to the GHC reviewer, "[t]here is no 2010 updated entry for this condition (or 2008 or 2009)." In fact, the "2007 entry [was] now listed as 'resolved' in the Snapshot section - resolved in 12/2007."

231. DxID also captured a diagnosis code for diabetes with neurological manifestation on the notion that the patient was separately diagnosed with polyneuropathy in diabetes. The GHC audit took issues with this capture, noting that the polyneuropathy in diabetes was "only documented as a probable diagnosis and also is only documented as a suspected complication from DM.[18] This is not acceptable as a definitive diagnosis."

232. In all, at least 17 of 20 diagnosis codes that DxID captured and GHC audited did not meet the ICD Guidelines, and thus CMS requirement, to only "[c]ode all documented conditions that coexist at the time of the encounter/visit, and require or affect patient care, treatment or management."

D. GHC adopted DxID's fraudulent coding recommendations for the 2010 DOS year submissions despite internal concerns.

233. Although GHC expressed concerns about DxID's aggressive coding recommendations, the financial incentives proved too attractive. The notes from the December 30, 2011, conference call indicate that "Dr. Tarnoff suggested DxID [should provide] estimate[d] value of what CKD, Old MI, and Hypoxia would be worth and the

[18] DM is shorthand for diabetes mellitus.

frequency within member population. *GHC would use this information internally to assess the risk and decide the next step*." Ex. L (emphasis added).

234. Gaffney provided estimates to Sather on the same day. The financial impact put the "Rough Projection [of] Annual Dollar Value" for CKD (or renal failure) at $2.5 million, for Old MI at $4.4 million, and for acute MI at $1.75 million. Although it did not include hypoxia, as requested by Dr. Tarnoff, the "rough" estimate for acute MI, Old MI, and CKD was $8.6 million in net revenue for GHC.

235. Despite concerns, including those raised during GHC's pre-submission audit, GHC's Associate General Counsel Mary Weiler emailed Gaffney on January 27, 2012, to "accept DxID 'rules' (policy and/or coding) for" various conditions, including Old MI.

236. GHC was persuaded, in part, by Gaffney's representation that her coding advice reflected industry practice, although Gaffney did not identify who in the industry followed such practice. As Weiler put it, "We agreed that we would submit the 3 diagnoses above in accord with what is considered standard practice (per DxID) for MA plans." [19]

237. Weiler, however, expressed GHC's "policy/coding issues surrounding 'Atherosclerosis of the aorta'" and "determined that these HCCs will not be submitted since these appear to be an incidental finding and only signed by a Radiologist."

238. Gaffney, however, would not give up on convincing GHC to accept DxID's recommendation to diagnose atherosclerosis from Incidental Findings. Despite not having any medical training, Gaffney protested the decision in a reply to GHC employees Weiler, Sather, Moses, Carrie Desimone, and Richard Magnuson, stating:

[19] The three diagnoses Weiler referred to were Old MI, unspecified alcohol dependence, and diabetes with neurological manifestations.

> Does anyone want to actually see the atherosclerosis notes, I am not sure they are all "incidental", in fact I am pretty sure that's not the case. Ur call, pretty much every diabetic who is overweight has it and there really isn't much you can do about it, except to monitor them-look at ur drug claims for lipitor or its replacements—maybe as a marker—I bet it's pretty big. Just saying. I know what these folks write down, it is actually not a risk at all based on your documentation. Let me know okay?

239. Gaffney's insistence reflected DxID's financial incentives. Since it would be paid 20 percent of the incremental revenue from CMS on contingent basis, it was in DxID's financial interest that GHC submits as many codes as DxID was able to capture.

240. GHC ultimately relented and accepted Gaffney's recommendation. On January 31, 2012, the day submissions for service year 2010 were due to CMS, a meeting was held between GHC and DxID.

241. Dr. Rappe, Dr. Tarnoff, Moses, Desimone, Sather, and Weiler attended on behalf of GHC. Gaffney attended for DxID. According to the meeting notes, a decision was made "[a]fter a very long discussion. We [GHC] decided to accept the DXid recommendation of submission of atherosclerosis." That reflected a reversal of the initial decision that Weiler conveyed to Gaffney a few days earlier. "Debbie [Sather] and Steve [Tarnoff] said they could both support Carrie [Desimone] in this decision. Mary [Weiler] stated this 'troubles me a little bit more' (than the prior decisions), but it 'passes the fraud test' and that we are 'at more risk of having money taken back.'"

242. As a result of using DxID's retrospective chart review process, GHC submitted 4,946 new diagnoses codes to CMS for the DOS year 2010. This was out of 17,000 targeted codes, for a capture rate of 29.1 percent.

243. This submission led to CMS paying over $12 million in incremental revenue to GHC.

244. GHC paid DxID a 20 percent contingency fee of over $2.4 million.

E. GHC staff continued to express concerns about DxID, but GHC executives wanted to deepen relationship with DxID.

245. After the submission of newly captured codes for DOS year 2010, GHC expressed interest in deepening its relationship with Gaffney and DxID. On February 2, 2012, Desimone wrote Gaffney that the "GHC core team (Debbie, me, Mary Weiler, Ric, Steven Tarnoff, Rhona Moses, and potentially a couple others) would like to take you up on your offer to come back to Seattle to share with us 'lessons learned from the review with GHC, opportunities you feel we are still missing' and to share your expertise again with us."

246. On February 13, 2012, Gaffney wrote to Desimone regarding potential changes to GHC's risk adjustment policies to allow GHC to capture more codes. To get around CMS rules on coding only conditions that were documented in the medical record as relevant to patient care during an encounter in the DOS year, particularly rules against coding from Past Medical History and other records that were not relevant to care in the DOS year, Gaffney said "[w]hat would make some real good sense . . . [is] to somehow force the docs to sign off on the snapshot every time they see the patient." She was recommending this approach because "[t]here is a ton of stuff in there but you need a face to face visit to validate the code."

247. According to Gaffney, a perfunctory signature after an encounter would allow coders like DxID to infer that the contents of the "snapshot" constituted documentation in the medical record that the conditions required or affected patient care, treatment, or management during an encounter in the DOS year and, thus, allow MAOs, like GHC, to submit the "ton of stuff" as diagnosis codes.

248. Around February 24, 2012, Sandy Lee and Dr. Rappe prepared a list, outlining the DxID coding guidance that conflicted with GHC's policies. The list reflected the lingering concern among a segment of GHC staff that the practices were problematic.

249. The list was divided into two sections:

DxID recommendations requiring GH[C] policy changes:

- Code systemic conditions when documented in past medical history, if recorded as part of imbedded problem list or listed in other sections of the note
- Code chronic conditions that are clearly present (e.g., amputation status) even if not documented in submission year – requires process change
- Code cachexia as chronic condition when documented in any part of the note (see item 1)

DxID recommendations are inconsistent with current GH[C] practices and leader decision needed:

- Code dx based on "incidental findings" not documented by treating provider in their encounter note with incidental finding impression made by radiologist reading image ordered usually for another reason i.e. Atherosclerosis noted in CXR ordered for cough
- Code dx based solely on embedded problem lists that aren't mentioned as "order entry" diagnosis or otherwise acknowledged in encounter note
- Code Hypoxia dx if O2 saturation level (88% or less) or oxygen is evident but provider does not use term "hypoxic" in encounter
- Code Old MI dx if qualifying condition is on problem list [but] not mention in encounter (see item 2)
- Code Old MI dx even without qualifying condition on problem list, but link to EKG
- Code dx if documented in past year(s) (e.g., alcoholism/substance abuse)
- Code dx if linked to Snapshot dx only
- Code dx if "probable, suspected, rule-out" in note
- Code major depression dx based on antidepressant use and/or PHQ-9 score

250. On February 26, 2012, Gaffney responded to Desimone and Sather with her recommendations, and advised that GHC should code in several circumstances that the then-existing GHC policy did not permit.

251. With respect to alcohol or substance dependence that "are not documented by the provider in the base [or service] year," Gaffney asserted that "[c]hronic conditions that never go away are codeable as secondary conditions when documentation of the condition in the medical record is available at the time of a F2F."[20] Thus, in Gaffney's incorrect view, alcohol and substance dependence can be inferred from prior year documentation that was purportedly available to the provider in the service year.

252. In addition to these recommendations, Gaffney continued to recommend that GHC code conditions listed on Problem Lists and to code Old MI from EKGs.

253. Additionally, and as discussed in more detail below, Gaffney recommended employing an addenda process whereby DxID would seek to create documentation after the fact and up to a year after a provider-patient encounter.

254. On February 29, 2012, DxID presented its "DxID Post-2010 Chart Review Outcomes." DxID's policy recommendations on Problem List and other diagnoses raised concern among some GHC physicians. After the presentation, Dr. Fred Brodsky, GHC's Associate Medical Director for Clinical Informatics, wrote an email to Dr. Rappe and Dr. Tarnoff stating, "I'm not 100% comfortable trolling EKG and CXR[21] interpretations for diagnoses." Rappe responded the following day agreeing, "I share the trepidation you have about using CXRs and EKGs as diagnosis sources."

[20] F2F refers to "face to face" encounter.

[21] CXR is shorthand for chest x-ray.

255. Nevertheless, GHC's executives evaluated DxID's arguments for coding policy changes in March 2012 and decided to adopt all but the recommendations related to Old MI and Incidental Findings.

256. DxID continued to push GHC to adopt those polices and, in an effort to persuade GHC, attached the projected monetary value to coding those diagnoses.

257. On April 6, 2012, Gaffney told Sather that "Old MI was worth [$1,324,000] in the audit - so we'll do everything we can to make sure it is clear that it really should be coded for a variety of reasons. Incidental findings is harder to quantify."

258. DxID was not a disinterested vendor who was merely acting in the interest of its client. It was motivated by the fact that its own revenue—a contingency fee of 20 percent—was tied to GHC's decision to submit as many codes as DxID captured to CMS for risk adjustment.

259. GHC sent DxID a document entitled "Outstanding Policies for Executive Sponsors" for their input. The document included "Coding and CMS Guidelines" for coding Old MI and Incidental Findings, which contradicted Gaffney's and DxID's recommendations.

260. Gaffney and DxID pushed back. Regarding Incidental Findings, GHC indicated that CMS's guidelines state: "'Do not submit medical records for dates of services that occurred outside of the data collection period'" and that "**[d]iagnostic radiology reports** are noted to be '**unacceptable sources of medical records**' for RADV audits." But Gaffney disagreed and responded that "Incidental findings should be documented and coded because they exist and may [] affect the clinical management of the patient." She further explained

that "ICD 9 Coding rules do specify that incidental diagnoses should be coded" and "CMS states that ICD9 guidelines must be followed."

261. Regarding coding "Old MI based on the EKG dx of Old MI," GHC again quoted CMS guidelines that warned against coding without documentation in the medical record that the condition was relevant to patient care during an encounter in the DOS year.

262. But Gaffney again disagreed. Without directly addressing the absence of documentation, Gaffney responded: "An old myocardial infarction needs to be documented and coded because it is significant condition and affects the long term management of the patient regardless whether the patient is currently experiencing problems or not."

F. GHC asked IH to vouch for DxID's coding practices.

263. Prior to submitting DxID's codes for DOS year 2011, GHC decided to obtain an independent review of DxID's work because GHC "staff . . . [were] struggling with getting comfortable with the vendor's interpretation of risk adjustment coding rules," and their struggle was "making moving forward with this work challenging."

264. Sather asked GHC's CEO Armstrong to reach out directly to IH to discuss whether IH "ever had any concerns with any of the policies" promoted by DxID.

265. When GHC's CEO Armstrong reached out to IH regarding DxID, IH CEO Cropp responded that IH has "been through similar discussions" and has been "very comfortable with [DxID's] interpretation after having a 3rd party weigh in on this to help stress test the assumptions." To portray DxID as acting reasonably, he contrasted IH and DxID to an unnamed "cross town rival who is using one of the most aggressive HCC coding vendors and is bringing in much more revenue PMPM than we are."

266. On November 12, 2012, Gaffney wrote an email to Sather citing various sources to support her arguments that GHC should implement DxID's coding policies as soon as possible. Gaffney falsely warned GHC: "Note that it is REQUIRED that MA plans MUST submit ALL diagnoses that affect risk adjustment."

267. Again, Gaffney tied the policies to the high revenue impact for GHC, stating, "We do expect that these files contain, using our standard methodologies, within the range of $20 million in risk related findings." Gaffney had a strong incentive to push GHC because DxID was in line to be paid 20 percent—approximately $4 million—of GHC recoveries based on DxID's work.

268. Ultimately, GHC agreed to use DxID for the 2011 chart review on November 30, 2012, but with two exceptions to DxID's policies: (1) incidental findings and (2) Old MI.

269. With respect to Incidental Findings, GHC said it would "not code diagnosis from incidental findings from radiologic reports that are not specifically diagnosed in a face to face visit."

270. With respect to Old MI, GHC noted that "the issue on this one seems to be coding from an EKG only" and subsequently decided that the "presence of EKG as [the] ONLY evidence confirming MI should not be submitted as confirmed diagnosis of old MI unless treating provider actually addressed EKG findings and status of patient in F2F visit."

271. Yet even after receiving direction from GHC that it was not accepting DxID's approach to coding Old MI from EKGs, DxID continued to do so.

272. Five days before the submission deadline, Sather elevated the Old MI issue to GHC executives, Scott Boyd, GHC's Vice President of Finance, and Paul Sherman, who had responsibility for CMS submissions, and advised them that Dr. Rappe and Ross still had

concerns about DxID. Sather also informed Boyd and Sherman that the value of the disputed records was about $2 million.

273. Other GHC clinicians reviewed the Old MI submissions captured by DxID and discovered high error rates including instances in which the patient did not have the condition. Just three days before the DOS year 2011 submissions were due, on January 28, 2013, Ross wrote an email to Dr. Rappe stating, "the provider reviewers have reviewed 47 old MIs. Of those 33 do not have the condition. So, we still have a 70% false positive rate with the DxID data."

274. A meeting was held on January 29, 2013, just two days before the submission, to advise GHC senior executives of ongoing issues with Old MI. Sather, Dr. Rappe, Ross, Sherman, and Boyd discussed three specific examples. Dr. Rappe advised the group that he determined the patients did not have an MI.

275. Boyd and Sherman decided to allow the HCCs to be submitted anyway. Boyd emailed Sherman stating that while he "can see the issue and the grayness," he is "inclined to view this as within the parameters of a decision that we have already made." Accordingly, "[i]t is still within the approach and risks we have agreed we should move forward with. I am fine with leaving in the submission." Sherman wrote back, "We're completely aligned."

276. Sherman then sent an email to Mark Szalwinski stating, "we need to decide by tomorrow at the latest. It's with old MI and some concerns that while we meet the documentation standard, all the patients probably didn't have an MI." Sherman nevertheless stated that "Scott B[oyd] and I are aligned that this is still within the risk parameters [] agreed to and we should let it ride." Szalwinski agreed, saying he was "ok with you and [S]cott proceeding ahead."

277. GHC submitted diagnosis codes to CMS based on DxID's retrospective chart review process for DOS year 2011, which resulted in additional payments from CMS $20 million. DxID received 20 percent of the additional revenue paid to GHC, or more than $4 million.

278. Given the extensive communications with GHC and their own experience in conducting retrospective chart review services, DxID and Gaffney, individually and collectively, knew or recklessly disregarded the fact that many of the diagnosis codes they caused to be submitted were false or otherwise unsupported.

279. Under the Overpayment Rule, "if an insurer learns a diagnosis it submitted to CMS for payment lacks support in the beneficiary's medical record, the insurer must refund the payment within sixty days." *See UnitedHealthcare*, 2021 U.S. App. LEXIS 24141, at *2.

280. The established process for refunding overpayment under the MA program is to delete invalid or unsupported diagnosis codes. Indeed, as alleged in Paragraphs 315 to 326, in 2013, IH deleted unsupported diagnosis codes for Old MI at the advice of Cognisight and repaid nearly $700,000 to CMS through the automated payment reconciliation process.

IV. IH, DxID, and Gaffney Submitted or Caused the Submission of False Claims to CMS.

281. As alleged above, under ICD Guidelines, which have been adopted by CMS, it is permissible to "[c]ode all documented conditions that coexist at the time of encounter/visit, and require or affect patient care, treatment or management." *See* FY14 ICD-10 Coding Guidelines; FY11 ICD-9 Coding Guidelines.

282. Documentation is at the core of Medicare Part C risk adjustment. It is mandatory. It is the evidence that a condition did, in fact, coexist at the time of the encounter

or visit and that the condition required or affected patient care, treatment, or management during the encounter or visit.

283. Conditions to be coded must be documented in the medical record as relevant to patient care during an encounter in the DOS year. *See UnitedHealthcare*, 2021 U.S. App. LEXIS 24141, at *3 ("Payments to the Medicare Advantage program depend on participating insurers accurately reporting to CMS their beneficiaries' salient demographic information and medically documented diagnosis codes."); *United States ex rel. Swoben v. United Healthcare Ins. Co.*, 848 F.3d 1161, 1168 (9th Cir. 2016) ("Each diagnosis code submitted must be supported by a properly documented medical record."); *United States ex rel. Ormsby v. Sutter Health*, 444 F. Supp. 3d 1010, 1025 (N.D. Cal. 2020) ("With respect to health status, CMS's HCC model relies on diagnosis codes documented by treating physicians during office visits and hospital outpatient and inpatient stays."); *id.* at 1067 ("A properly documented medical record must support each diagnosis code.").

284. Defendants, however, knowingly coded conditions that were not documented in the medical record as relevant to patient care during an encounter in the DOS year by, among other things, taking old information, such as old lab reports or patient history from past years, and combining it with unrelated encounters in the DOS year to claim that a condition required or affected patient care, treatment, or management.

285. Defendants submitted diagnosis codes to CMS for risk adjustment payment for conditions that they knew were neither diagnosed nor documented as coexisting during the DOS year for their own pecuniary benefits.

286. To carry out this scheme, DxID mined medical records of IH's MA Plan enrollees for any indication of risk-adjusting conditions in old Problem Lists, Past Medical

History, diagnostic test results, and/or DME orders. These records were generated in previous years, sometimes a decade or longer before, by other providers. Some, like Problem Lists, were generated electronically through algorithms. If DxID found a risk-adjusting condition, or even just something approximating a risk-adjusting condition, during this process, it would code the condition based on DxID's faulty assumption—without evidence—that the old or automated record was available to the enrollee's provider during the DOS year encounter. Although the belief that the record was available did not satisfy CMS's documentation requirement, DxID submitted these codes to IH, which submitted them to CMS.

287. At other times, Defendants captured diagnoses that were not even mentioned in labs or records from previous years, based on the assumption—also without evidence—that the conditions were common among senior citizens.

A. IH submitted diagnosis codes captured through DxID's fraudulent chart review program.

i. DxID coded from Problem Lists, and IH submitted the codes to CMS for risk adjustment.

288. For DOS years 2011 through at least 2017, DxID coded from Problem Lists only, and IH submitted the codes to CMS for risk adjustment payment.

289. As explained above, Problem Lists are commonly used to predict a condition that may affect a patient based on symptoms, medications, age, gender, and any other algorithmic factors used in the system in which the Problem List was generated. But while useful, Problem Lists do not, in and of themselves, substantiate the existence of a condition, let alone the coexistence of the condition during a DOS year encounter. Indeed, Problem Lists from past years are even less reliable.

290. Notwithstanding the requirement that a diagnosis code must be documented in the medical record as relevant to patient care during an encounter in the DOS year, not merely mentioned, suggested, or inferred anywhere from records from past years, DxID's practice was to capture diagnoses solely from Problem Lists without regard for whether a condition was documented in the medical record as relevant to patient care during an encounter in the DOS year..

291. DxID and Gaffney implemented this policy while performing the chart reviews for IH. On January 21, 2013, Paul Starowicz of DxID emailed Gaffney to ask, "When a standard reviewer finds a diagnosis on the chart problem list . . . . Regardless, if they find additional management [of the diagnosis] documented or not, I would want them to click the 'Yes' to Diagnosis found . . . . Then the QC process can determine [if it] should be submitted or addended. Am I correct . . . ?" Gaffney answered, "Yes!"

292. Gaffney reiterated the policy and practice in an email on February 26, 2014, to IH's external auditors at Deloitte, while copying, among others, Michael Faso and George Wands: "When a problem list is in an electronic medical record, embedded within a note at a f2f visit . . . and the doctor is signing the note etc. That is to our knowledge the indication of the diagnosis being made [by] the doctor at a face 2 face . . . and is submittable." In essence, Gaffney was explaining DxID's practice of taking a laundry list of conditions mentioned on old Problem Lists and coding the conditions.

293. Even assuming it was true that an old Problem List was "embedded" in a DOS year encounter note, that does not substantiate that the condition was diagnosed or was a factor in the encounter. Conditions are frequently added, often electronically or automatically, to Problem Lists. Nevertheless, Defendants justified submitting the code for

risk adjustment on the assumption that a provider could have, theoretically, reviewed the Problem List and possibly considered the laundry list of conditions during an encounter that may have had nothing to do with any of the conditions on the list. The regulations, however, call for documentation, not inferences or assumptions.

294. Gaffney knew that her recommendation to IH to code from Problem Lists contradicted the prevailing rules, and she said so. On January 29, 2014, Gaffney was telling another MAO (New West Health Services dba New West Medicare) something completely different than what she was telling IH. The MAO instructed Gaffney and DxID "to make sure that DxID is not pulling data from any records that would not support the findings should we be audited. These documents would include labs, radiology, phone notes, problem lists, etc." Gaffney prepared a draft response stating, "We can assure you . . . that we are well aware of the rules regarding appropriate submissions and do not use any radiology notes[,] labs[,] call notes[,] problems lists[,] etc." This email was later sent to the MAO by another DxID employee.

295. For IH, however, DxID did code from radiology notes, labs, and Problem Lists, among other inadequate sources of diagnoses.

296. From at least DOS year 2010 through at least DOS year 2017, DxID coded from Problem Lists, and IH submitted the codes to CMS for risk adjustment payment, including in the following, non-exhaustive, examples:

a. **Patient A**: DxID captured and IH submitted a diagnosis code for CKD in DOS year 2012 for this member based solely on a notation in the Problem List without documentation in the medical record that CKD was relevant to the patient's care during any encounter in DOS year 2012. IH did not subsequently delete the code. As a result, CMS paid IH an additional $2,236.54 in Payment Year 2013.

b. **Patient B**: DxID captured and IH submitted a diagnosis code for "Paroxysmal Ventricular Tachycardia" in DOS year 2013 for this member based solely on inclusion of the condition in the Problem List without

documentation in the medical record that the condition was relevant to the patient's care during any encounter in DOS year 2013. IH did not subsequently delete the code. As a result, CMS paid IH an additional $2,594.70 in Payment Year 2014.

c. **Patient C**: DxID captured and IH submitted diagnosis codes for Old MI in DOS year 2013 for this member based solely on a Problem List that noted an undated heart attack without documentation in the medical record that Old MI was relevant to the patient's care during any encounter in DOS year 2013. IH did not subsequently delete the code. As a result, CMS paid IH an additional $336.94 in Payment Year 2014.

d. **Patient D**: DxID captured and IH submitted a diagnosis code for COPD in DOS year 2015 for this member based solely on the Problem List without documentation in the medical record that the condition was relevant to the patient's care during any encounter in DOS year 2015. IH did not subsequently delete the code. As a result, CMS paid IH an additional $2,659.63 in Payment Year 2016.

e. **Patient E**: DxID captured and IH submitted a diagnosis code for "Pulmonary hypertension, secondary or unspecified" in DOS year 2016 for this member based solely on the Problem List dated June 14, 2004 without documentation in the medical record that the condition was relevant to the patient's care during any encounter in DOS year 2016. IH did not subsequently delete the code. As a result, CMS paid IH an additional $1,383.17 in Payment Year 2017.

ii. DxID coded from Past Medical History, and IH submitted the codes to CMS for risk adjustment.

297. DxID also coded from Past Medical History, despite Gaffney's knowledge that this was impermissible.

298. Gaffney expressed her knowledge in an email to GHC on February 13, 2012, when she wrote: "So - for example - if something is listed in past medical history – you cannot code it according to CMS's straight up interpretation of coding rules." She further explained that "Past medical history as a title is not going to hold up [from a] coding standpoint, as it isn't ALWAYS true."

299. As explained in Paragraph 155 above, the ICD forbids coding "conditions that were previously treated and no longer exist" and explicitly cautions that "history codes . . .

may be used as secondary codes if the historical condition or family history has an impact on current care or influences treatment."

300. Nevertheless, as further alleged in Paragraph 154, under DxID's GCP, "Continuing Chronic conditions . . . that are documented as 'history of' will be coded. Continuing Chronic diagnoses listed in the 'Past Medical History' will be coded."

301. On July 10, 2012, a DxID employee asked Gaffney to "walk through each scenario so we can know what you want to do" regarding coding. There were six fact scenarios, and Gaffney was asked to decide whether to code from four sources of information: "Problem list," "Assessment," "Past Medical History," and "Review of systems."

302. Gaffney replied the same day, inserting her response after each record type. Of particular note, Gaffney responded:

> Chronic conditions that don't resolve, with no sign of treatment:
>
> Problem list: Electronic embedded YES
> Assessment: Y
> Past Medical History: Y
> Review of systems: Y[22]

303. Despite her acknowledgement that "CMS's straight up interpretation of coding rules" would not allow coding from Past Medical History alone, Gaffney instructed DxID coders to do just that when she indicated that "Chronic conditions that don't resolve, *with no sign of treatment*" should be coded from Past Medical History alone.

[22] Gaffney also provided a response for the scenario: "Chronic conditions that may resolve, with no sign of treatment." Although she instructed that Past Medical History alone would not support adding the condition, she did state that a condition could be added based solely on a Problem List entry.

304. DxID did, in fact, code from Past Medical History alone, and IH submitted these codes to CMS for risk adjustment payment from at least DOS year 2010 through at least DOS year 2017, including in the following, non-exhaustive, examples:

a. **Patient F**: DxID captured and IH submitted a diagnosis code for Old MI in DOS year 2011 for this member based solely on Past Medical History that stated that the patient had a heart attack in March of 2002 without documentation that Old MI was relevant to the patient's care in DOS year 2011. IH did not subsequently delete the code. As a result, CMS paid IH an additional $2,072.45 in Payment Year 2012.

b. **Patient G**: DxID captured and IH submitted a diagnosis code for Old MI in DOS year 2013 for this member based solely on Past Medical History that stated that the patient had a heart attack in 1984 without documentation that Old MI was relevant to the patient's care in DOS year 2013. IH did not subsequently delete the code. As a result, CMS paid IH an additional $327.26 in Payment Year 2014.

c. **Patient H**: DxID captured and IH submitted a diagnosis code for Old MI in DOS year 2013 for this member based solely on Past Medical History that stated that the patient had a heart attack in 1989 without documentation in the medical record that Old MI was relevant to the patient's care in DOS year 2013. The Past Medical History was last updated in 2011. Furthermore, the provider did not sign the notes from the patient encounter. IH did not subsequently delete the code. As a result, CMS paid IH an additional $299.37 in Payment Year 2014.

d. **Patient I**: DxID captured and IH submitted a diagnosis code for "Morbid Obesity" in DOS year 2015 for this member based solely on inclusion of the condition in the Past Medical History without documentation in the medical record that the condition was relevant to the patient's care in DOS year 2015. The Past Medical History noted that the member underwent gastric bypass surgery in 2005 for morbid obesity. IH did not subsequently delete the code. As a result, CMS paid IH an additional $2,736.20 in Payment Year 2016.

iii. DxID coded from labs, and IH submitted the codes to CMS for risk adjustment.

305. DxID coded from labs only, and IH submitted the codes to CMS for risk adjustment, without regard for whether the lab results represented documentation in the medical record that the condition required or affected patient care, treatment, or management in the DOS year.

1. Defendants coded and submitted CKD from lab results.

306. Defendants coded Chronic Kidney Disease ("CKD") from lab results, such as results for Glomerular Filtration Rate ("GFR").

307. Gaffney frequently advocated for DxID coding from these prohibited sources, and IH went along with the practice.

308. In January 2012, for example, Gaffney sought confirmation from IH employees, including Tracy and Spagna, whether "you would like us to capture renal failure, CKD and specified levels of CKD on all members who" either (1) "Have the diagnosis written in an encounter note specifically" or (2) "Have the lab values that determine CKD . . .," which is "available to the physician at the time of a face to face encounter AND have . . . initialed or signed (All are mechanically dated)."

309. In essence, Gaffney was asking whether IH would hold DxID to CMS rules of requiring documentation of CKD in the DOS year encounter notes or whether it would allow DxID to flout the rules and code from "lab values" that were available to (although not necessarily reviewed by) a provider at a face-to-face encounter.

310. In a follow up email on January 16, 2012, Gaffney elaborated that she was "only talking about documentation parameters, not whether . . . members have the disease." Despite having no clinical experience, Gaffney assured IH that "they have it." She was asking IH "just how much room are you comfortable with if - by some chance they went to appeal." With CKD, she stated (incorrectly) that "labs being available at the time of a face to face allows assumption . . . ." Even as she was advocating coding the condition from lab values only, Gaffney observed that "lab values as the ONLY evidence of the disease, would not pass RADV."

311. Again, in a May 14, 2013, email to IH personnel, including Tracy, Gaffney—who has no clinical training or experience—asserted without basis that CKD "is identifiable only from lab data"; that DxID "audit[s] all charts for evidence of CKD, which will be either signed and dated labs at whatever level"; and "[p]retty much everyone over age 70 has some level of CKD - it is generally not apparent in testing until Stage 3."[23]

312. Under CMS rules, the acceptable proof that a condition existed and can be coded during a service year is that it was documented as existing during that service year encounter—not whether Gaffney believed the condition existed. IH ignored the rules and, instead, relied on the justifications that Gaffney provided.

313. From at least DOS year 2010 through at least DOS year 2017, DxID coded CKD from labs only, and IH submitted the codes to CMS for risk adjustment payment, including in the following, non-exhaustive, examples:

a. **Patient J**: DxID captured and IH submitted a diagnosis code for CKD in DOS year 2012 for this member based solely on lab results without documentation in the medical record that CKD was relevant to the patient's care in DOS year 2012. IH did not subsequently delete this code. As a result, CMS paid IH an additional $2,339.28 in Payment Year 2013.

b. **Patient K**: DxID captured and IH submitted a diagnosis code for atherosclerosis of the aorta in DOS year 2012 for this member based solely on an x-ray from 2010 that was available to the provider at the time of the encounter, and without documentation There is no documentation in the medical record that this condition was relevant to the patient's care in DOS year2012. IH did not subsequently delete the code. As a result, CMS paid IH an additional $1,238.60 in Payment Year 2013.

c. **Patient L**: DxID captured and IH submitted a diagnosis code for CKD in DOS year 2014 for this member based solely on labs without documentation in the medical record that CKD was relevant to the patient's care in DOS year2014. IH did not subsequently delete these codes. As a result, CMS paid IH an additional $1,501.08 in Payment Year 2015.

[23] Normally, providers diagnose CKD from abnormal Glomerular Filtration Rates (GFR), often measuring consecutive GFRs within a short period of time. CKD cannot be coded for risk adjustment purposes based on mere supposition that an older person is likely to have deteriorating kidney function.

2. IH was aware that it could not code CKD from lab results.

314. IH was aware that it was not permitted to code CKD from lab results. In or around 2010, IH stopped using Cognisight's services, acquired the core human assets of Cognisight (*i.e.*, Gaffney, Coughlin, and Haughton), and formed DxID with those assets. This allowed the policies and practices at Cognisight to roll over to DxID seamlessly.

315. In May 2013, Cognisight sent a notice to IH that it was abandoning its practice of coding CKD from GFRs and recommended that IH should delete corresponding codes that Cognisight captured for IH, which IH submitted to CMS for DOS year 2010.

316. IH followed Cognisight's recommendation and deleted the CKD codes for the 2010 DOS. As a result of the deletion, IH repaid CMS nearly $700,000, while Cognisight refunded its 20 percent commission to IH.

317. IH's deletion and repayment in 2013 for the 2010 DOS year was prompted by a CMS notice of May 3, 2013, to all MAOs, where CMS reminded MAOs of their obligation "to report and return overpayments to CMS." To facilitate returning overpayments, CMS provided a grace period for the 2010 service year by "giving MA organizations the opportunity to delete diagnoses submitted in error prior to sampling for the 2011 RADV audits." CMS said it "will allow the deletions of diagnoses for PY 2011[24] that are submitted through May 31, 2013." *See* CMS Mem., "Payment Year (PY) 2011 Payment Data Correction and Risk Adjustment Data Validation (RADV)," by Cheri Rice (May 3, 2013).

318. Although IH would have received this notice directly, Cognisight brought it to IH's attention on May 22, 2013. Cognisight also included a letter dated May 20, 2013, that

[24] Payment year or PY 2011 PMPM payments are based on service year 2010.

was addressed to IH's Tracy, where Cognisight explained that it was recommending deleting codes for CKD that were captured from labs only. The letter, signed by Kim Browning, Executive Vice President of Cognisight, explained, "Until recently, our practice has been to submit ICD-9 Code 585.9 through RAPS submission in those instances where we found consecutive laboratory reports . . . with abnormal . . . [GFR]. The practice was limited to only CKD. GFRs are the only way to diagnose CKD." Though it was not stated in the letter, the "practice" described in Browning's letter was instituted and implemented primarily by Gaffney.

319. Browning further stated in her letter, "CMS historically has taken position that, in general, medical lab documentation alone is insufficient to support coding for MA risk adjustment purposes, and that abnormal lab findings should not be coded and reported unless the physician has indicated their clinical significance. . . . Accordingly, although we believe that our original position was and remains well reasoned, we recommend as a matter of prudence and risk management, given the possibility of contrary reasoning with CMS, that Independent Health delete the codes at issue prior to May 31, 2013." Browning went on to disclose that Cognisight has "identified 240 diagnoses submitted in prior RAPS submissions for PY 2011 that would need to be deleted."

320. On May 31, 2013, Browning followed up with Tracy by email, stating, "In 2010, there were 845 total CKD dx submitted to CMS. 240 were substantiated by labs only. 605 were fully substantiated."

321. Tracy forwarded the email to Gaffney and DxID.

322. Ultimately, IH followed Cognisight's recommendation and submitted the 240 codes to CMS for deletion.

323. In October 2013, Tracy confirmed to Cognisight that CMS had deleted the codes and the risk adjustment dollar value was $680,953.41. CMS deducted this overpayment from later payments to IH.

324. Likewise, Cognisight refunded its portion of the repayment to IH, which covered the fee it received for capturing the codes in the first place.

325. Despite receiving actual notice that it should not code CKD from lab values and consequently had to withdraw the codes for DOS year 2010, IH did not withdraw or delete the codes submitted for DOS years 2011 and 2012, nor did IH and DxID cease the practice of coding CKD from lab values only from DOS year 2013 onward. *See supra* ¶ 313.

326. IH submitted the DxID CKD codes *after* deleting the Cognisight codes with full knowledge that DxID's practice was to code CKD from labs alone. *See supra* ¶ 311.

3. Defendants coded and submitted Old MI from EKG results.

327. Defendants also captured Old MIs from EKGs in the absence of documentation in the medical record that the Old MI or EKG required or affected patient care, treatment, or management during an encounter in the DOS year. In fact, the EKGs for which DxID captured Old MI codes were, in many cases, years or even decades old.

328. As alleged in Paragraph 162, "DxID's Diagnosis Specific Chronic Condition Coding Policy" falsely asserted that "electrocardiograms can be used to support the presence of an old myocardial infarction."

329. On January 18, 2012, DxID's clinical coding manager, Paul Starowicz, sent an email to Gaffney and others, attaching a document that he described as "the handout given to the IH contract folks" regarding capturing "Old MI via confirmed EKG screen shot." The attachment, which contained DxID's coding "tips," stated, "When utilizing an EKG for an

Old MI, include other supporting information such as documented heart disease listed in audit year encounter notes and medical management of Old MI. Document if these items are present or not."

330. From at least DOS year 2010 through at least DOS year 2017, DxID coded Old MI solely from EKGs, and IH submitted the codes to CMS for risk adjustment payment, including in the following, non-exhaustive, examples:

a. **Patient M**: DxID captured and IH submitted a diagnosis code for Old MI in DOS year 2012 for this member. The code was added based solely on an EKG from 2005 without documentation that Old MI was relevant to the patient's care in DOS year 2012. DxID appears to have assumed, without documentary support, that the EKG results were available to the provider at the time of the encounter. IH did not subsequently delete the code. As a result, CMS paid IH an additional $1,440.11 in Payment Year 2013.

b. **Patient N**: DxID captured and IH submitted a diagnosis code for Old MI in DOS year 2012 for this member based solely on an EKG from 2010 without documentation that Old MI was relevant to the patient's care in DOS year 2012. DxID appears to have assumed, without documentary support, that the EKG results were available to the providers at the time of the encounters. IH did not subsequently delete these codes. As a result, CMS paid IH an additional $1,447.47 in Payment Year 2013.

c. **Patient O**: DxID captured and IH submitted a diagnosis code for Old MI in DOS year 2014 for this member based solely on an EKG from 2012 without documentation that Old MI was relevant to the patient's care in DOS year 2012. Furthermore, the encounter notes were not signed by a provider. IH did not subsequently delete the code. As a result, CMS paid IH an additional $773.43 in Payment Year 2015.

iv. DxID coded from DME Orders, and IH submitted the codes to CMS for risk adjustment.

331. DxID coded diagnoses from DME orders alone, and IH submitted the codes to CMS for risk adjustment payments. Hypoxemia and hypoxia were the most common conditions improperly coded from oxygen use.

332. Hypoxemia refers to low level of oxygen in the blood, while hypoxia refers to low oxygen level in any tissue or organ or the body as a whole. Hypoxemia can cause hypoxia, although hypoxia can have other derivations, such as anemia.[25]

333. DME that provides oxygen to a patient is used to treat hypoxemia or hypoxia, but the presence in the medical record of a prescription order for oxygen does not, without more, substantiate the existence of hypoxia or hypoxemia for risk adjustment purposes. Oxygen can be used to treat conditions other than hypoxia or hypoxemia, such as obstructive sleep apnea in some limited circumstances. More importantly, a provider can prescribe oxygen for its indicated purposes or for non-indicated or off-label purposes. As such, the acceptable documentation for the coexistence of hypoxia or hypoxemia during a service year encounter is the oxygen level in the medical record or express diagnosis by a provider.

334. DxID knew the rules and clinical standards but refused to follow them. When asking IH for permission to code hypoxemia/hypoxia from DME (oxygen) in December of 2011, Gaffney acknowledged that "CMS says (for correct medical record documentation content) that in a physician[']s office, the diagnosis must be clearly stated or easily inferred in order to code it."

335. Yet, Gaffney took the unreasonable position that hypoxia or hypoxemia could be inferred from oxygen orders, despite recognizing that hypoxia may not be the only condition for which oxygen is prescribed. As she explained in the context of "reviewing for the addendum's in the office," when a record "says that the person needs or uses oxygen but does not say hypoxia, it may [say for COPD,] or emphysema or nothing at all." However, Gaffney justified her approach coding hypoxia and hypoxemia from oxygen orders during

[25] Hypoxia and hypoxemia can be used interchangeably in this context, as they map to the same HCC.

the retrospective chart reviews by declaring that "there is no reason to give someone oxygen if they are not hypoxic."

336. Tracy approved of Gaffney and DxID's approach to coding hypoxia and hypoxemia from oxygen, writing, "My feedback is if it is 'easily inferred' and clinically makes sense, then we should code it and can defend it that way if it came up in an audit."

337. In November 2013, Gaffney again affirmed DxID's improper use of DME orders to capture conditions that are otherwise unsupported in medical records. In an email to DxID staff on November 12, 2013, Gaffney said that DxID needed to obtain the professional DME claims files from MAOs like IH. She wrote, "We benefit [from] having the DME because there is a diagnosis in the claim – because sometimes – not often – it is the only reference to a disease."

338. From at least DOS year 2010 through at least DOS year 2017, DxID coded conditions such as hypoxia from oxygen orders only, including in the following, non-exhaustive, examples:

a. **Patient P**: DxID captured and IH submitted a diagnosis codes for hypoxemia for this member in DOS year 2011 based solely on the patient being place on oxygen without documentation that the hypoxemia was relevant to the patient's care in DOS year 2011. IH did not subsequently delete the code. As a result, CMS paid IH an additional $3,611.07 in Payment Year 2012.

b. **Patient Q**: DxID captured and IH submitted a diagnosis codes for hypoxemia for this member in DOS year 2013 based solely on the patient being place on oxygen without documentation that the hypoxemia was relevant to the patient's care in DOS year 2013. IH did not subsequently delete the code. As a result, CMS paid IH an additional $167.43 in Payment Year 2014.

c. **Patient R**: DxID captured and IH submitted a diagnosis codes for hypoxemia for this member in DOS year 2014 based solely on the patient being place on oxygen without documentation that hypoxemia was relevant to the patient's care in the DOS year 2014. IH did not subsequently delete the code. As a result, CMS paid IH an additional $2,489.60 in Payment Year 2015.

d. **Patient S**: DxID captured and IH submitted a diagnosis codes for hypoxemia for this member in DOS year 2014 based solely on the patient being place on oxygen without documentation that hypoxemia was relevant to the patient's care in DOS year 2014. IH did not subsequently delete the code. As a result, CMS paid IH an additional $612.90 in Payment Year 2015.

B. IH approved of DxID's improper addenda process and submitted diagnosis codes based on DxID's addenda process.

i. DxID's Improper Addenda Process.

339. In addition to implementing fraudulent coding policies that led to the submission of unsupported diagnosis codes during the retrospective chart review program, DxID also implemented an addenda process to capture diagnosis codes for IH's submission to CMS.

340. DxID's addenda process complemented its retrospective chart review program. DxID captured diagnosis codes by supplementing a patient's medical records through the use of an addendum to the medical record. As Gaffney put it, "when the content of [a retrospective] chart indicates that more specific documentation might be required on a particular diagnosis, then an addendum is created."

341. Generally, medical record addenda are a means by which medical record entries can be updated, corrected, or supplemented. An addendum can be used to amend a patient's medical records to include services rendered but omitted or to include results of, or diagnosis from, diagnostic tests requested by a provider but performed after an encounter. An addendum can also be used to clarify or correct a medical record that contains conflicting or insufficient information.

342. Under CMS rules and guidance, as well as industry practice, addenda have legitimate uses. CMS recognizes the use of an addendum "to the extent it provides clarification and is consistent with the other medical record documentation." *See* CMS policy

clarification memo (Oct. 11, 2001), at PRO 2001-13; *see also* CMS, *Medicare Program Integrity Manual*, Ch. 3, § 3.3.2.5(A); CMS, *2008 Risk Adjustment Data Technical Assistance Participant Guide* § 6.4.2 (stating that any addendum to a medical record must be "related to a service that was provided" in the prior provider-beneficiary encounter).

343. An addendum must therefore be "related to a service that was provided" during a DOS year encounter;[26] the addendum request form should not be leading;[27] the addendum must be timely;[28] and it must "bear the current date of that entry and is signed by the person making the addition or the change."[29]

344. DxID was explicitly advised of the limited legitimate uses of addenda by its legal counsel on a June 13, 2012 call in which DxID employees, including Gaffney and Coughlin, were told that "[t]he addendum note is intended [to] clarify the specificity of disease where the available documentation could be more clear, precise or complete . . . ."

345. Nonetheless, DxID recommended, and IH adopted, policies that went well beyond the limited and legitimate uses of addenda. Rather than ensure accuracy in medical records, DxID's addenda process was specifically crafted to capture lucrative risk adjustment diagnoses to increase payments from CMS. As Gaffney explained to Faso in a September 6,

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[26] CMS, *2008 Risk Adjustment Data Technical Assistance Participation Guide* § 6.4.2.

[27] CMS, *Quality Improvement Manual*, Ch. 4, § 4130; *see also* AHIMA Practice Brief, *Guidelines for Achieving a Compliant Query Practice* (2016 Update) (An impermissibly leading query is "one that is not supported by the clinical elements in the health record and/or directs a provider to a specific diagnosis or procedure.").

[28] CMS, *Risk Adjustment Training for Medicare Advantage Organizations Participant Guide* (2008), § 3.5.1 ("must report claims and encounter information in a timely manner, generally within 30 days of the date of service"), § 6.4.2 (discussing addenda made "several days after the patient encounter").

[29] CMS, *Calendar Year 2005 Medicare Advantage Risk Adjustment Data Validation Frequently Asked Questions* (Aug. 17, 2006) ("Addenda/Amendments to medical records must be made in a timely manner. For purposes of validation, changes or updates to medical records are typically made within 60 (and typically 30) days of a face-to-face visit.").

2011 email, the purpose of the addenda program was to obtain "an increase in recoveries" from CMS.

346. To implement the addenda process, DxID first analyzed a beneficiary's medical record using data analytics to identify whether there was a potential marker of conditions with high risk adjustment reimbursement rates that had not been recorded by the treating physician.

347. After identifying such a record, DxID "queried" the patient's provider, using a medical record addendum ("MRA") form. Often MRA forms were sent many months, and even up to a year, after the patient encounter for which the addendum would serve as a supplement.

348. The MRA form offered a list of conditions for the provider to check off. Although the provider supposedly had a choice to check off or rule out a condition, as discussed below, the forms were presented in such a leading (and misleading) way as to strongly suggest that the provider should check off the condition. Compounding this issue was the fact that DxID did not know if the condition existed at the time of the visit; rather, conditions were added to MRA forms based on analytics or simply because they were valuable to submit to CMS.

349. To encourage providers to review, sign, and return MRA forms, DxID paid providers a $25 fee per MRA.

350. When a provider signed and returned the MRA form, DxID would then attach the form to the medical record as support for additional diagnosis codes, which it would capture and IH would submit to CMS.

351. If the provider did not complete the MRA on their own, DxID would increase the pressure on the provider. With the permission of IH, DxID personnel were dispatched to the provider's medical office to review the beneficiary's medical records and check off diagnoses on the MRA forms, and then present a pre-filled form to the provider to sign.

352. Gaffney described DxID's addenda process in detail to GHC's Debbie Sather on May 30, 2012, when she was trying to convince GHC to adopt it. In an exchange with Sather, Gaffney claimed the following:

a. DxID's addenda process is about half of DxID's overall chart review program "for other clients," including IH.

b. That DxID would "bundle the diabetes and renal . . . ." and "put CKD on each [query] if none has been captured, just because [it's] prevalent- we don't have to if you don't want to - but [it's] worth it."

c. It takes providers "maybe 2-3 minutes per form" to fill out and DxID would "be happy to pay for the time ([$]25 per [MRA]) if that helps . . . ."

d. DxID's outside legal counsel has said that there is "nothing anywhere that says there is a timeline on late entries - this is mainly chronic conditions."

e. DxID does not have any client "who has been through both processes [retrospective chart reviews and the addenda process] yet except IH."

353. When Sather asked for further clarification of the addenda process, Gaffney replied in a lengthy email, noting, among other things, that:

a. DxID included conditions on the MRA forms based on (i) "Analytic Targets"; (ii) "Review of the record in total - so we find things that weren't in the analytics but are collectively apparent in the record"; (iii) "Shot guns - renal

failure when [it's] not listed anywhere"; (iv) "Things we are trying to correct - ex. The CVA[30] thing - when it should be changed to late effects or hemiplegia" or "Major depression that really isn't substantiated by the record to Major Depression in remission" or "alcoholic – to Alcohol dependence" or "Asthma or COPD / Emphysema to get the right thing documented with clarity."[31]

b. "The addendum's generally have more than one diagnosis on them - some will be correct, some not correct."

c. She expected at least 88 percent of providers would return MRA forms to GHC, but that the percent will increase if DxID pays doctors to review MRA forms. As Gaffney explained: "my other large client [*i.e.*, IH] is at 99%, [for] smaller clients its between 88 - 95 in my past life [*i.e.* at Cognisight] - but I pay the docs."

d. "The average recovery on addendum's is [$]1K per [MRA form] sent - that is what we have seen in the past - pretty much every time." And even if only 3 out of 10 MRA forms sent out come back, "its worth thousands to the plan."

354. GHC declined to adopt DxID's addenda process.

355. In contrast, IH, which had used the same services with Cognisight, relied on DxID's addenda process to complement the retrospective chart review program and, from

[30] CVA likely refers to cerebrovascular accident, commonly known as a stroke.

[31] Generally, asthma does not risk adjust, while COPD does. In fact, around the time of this email, in 2012, COPD had a community risk score of 0.340. So, in context, it appears that Gaffney was talking about converting asthma diagnoses (which carry no further compensation under MA) to COPD (which does). Moreover, if the enrollee is also diagnosed with congestive heart failure, there would be an additional community disease interaction factor of 0.273.

DOS years 2010 to at least 2017, submitted more than 125,000 addenda to support hundreds of thousands of risk-adjusting diagnosis codes that were submitted to CMS.

356. DxID's addenda process was fraudulent and unreliable in at least two ways:

a. First, DxID used impermissibly leading MRA forms that introduced new information or conditions that were neither indicated nor even suggested in the medical record or sought to up-code conditions that were documented during the patient encounter to more severe conditions, which were of greater value to IH. *See* CMS, *Quality Improvement Manual*, Ch. 4, § 4130 (explaining that additional review by a physician is necessary "[i]f the physician query form is leading in nature or if it introduces new information").

b. Second, DxID relied on impermissibly late addenda to support diagnosis codes. Specifically, DxID relied on MRA forms that they sent to providers many months, and up to a year, after the patient encounter.

ii. DxID and IH used impermissibly leading MRA forms.

357. DxID used leading MRA forms, which directed providers to a specific diagnosis or procedure for which there was little or no support in the medical record.

358. As Gaffney noted in her correspondence with Sather, DxID added conditions on the MRA form by, among other ways, using analytics or simply a "shot gun" approach in which it added valuable conditions without regard for whether there was any reason to suspect the condition existed based on a patient's medical history.

359. For example, DxID included CKD (or renal failure) on all MRA forms in the absence of any documentation suggesting that a patient suffered from those conditions.

360. This was a practice that DxID carried over from Cognisight. Cognisight regularly suggested CKD as a condition on query forms without any basis for including it. As Gaffney admitted during her time at Cognisight, "CKD was populated . . . on all [query forms] when we are addending anyway, so that we can capture it without lab data available."

361. IH's Tracy also explained, in a June 25, 2009 email, that Cognisight's approach was to ask reviewers (*i.e.*, providers) to look to add CKD on charts "because the lab data was sparse and did not want to miss an opportunity. So, based on the charts reviewed, this was always part of what was validated and reviewed."

362. Gaffney confirmed that DxID carried over the practice of including certain conditions on the MRA forms as a matter of practice in an email to IH's Faso on November 3, 2011, in which Gaffney was responding to concerns raised about DxID's addenda process. While claiming that "[e]ach addendum is specific to the patient," Gaffney admitted that DxID "do[es] load in renal failure on any patient that has not had renal failure submitted on all forms, just in case, as it is not documented in claims very often at specific levels and because it is worth a ton of money to IH and the majority of people [over] 70 have it at some level."

363. Renal failure was indeed "worth a ton of money to IH." It is the most severe form of chronic kidney disease, and in or around 2011, renal failure mapped on to HCC 135, which had a community risk adjustment factor of 0.617.[32] Thus, for every patient that was diagnosed with that condition, IH received at least 161.7 percent in PMPM payment, plus additional increases for disease interactions, where applicable.

[32] Renal failure mapped to HCC 131 in 2009 for a RAF score of 0.368.

364. During the same exchange, Gaffney attached a sample addendum that she described as DxID's final version, which asked a provider to check yes or no whether certain listed "diagnoses were considered, treated, or recognized as pertinent in the consideration of the care and treatment of" the patient. The sample MRA form listed several highly compensated diagnoses, including CKD. *Id.*

365. Gaffney again confirmed the "shot gun" approach in an email of May 30, 2012, to GHC's Sather, where Gaffney explained that DxID included on MRA forms "renal failure when [it is] not listed anywhere" in the medical records and that DxID "will put CKD on each [MRA form] if none has been captured, just because [it is] prevalent" and "[it is] worth it."

366. In addition to including conditions on MRA forms for which there was no support in the patient's medical records, DxID's MRA forms were presented to providers in such a way as to suggest that the provider had simply missed documenting the condition during the relevant patient encounter.

367. For example, a query form for an encounter on September 13, 2012, which was signed by a provider nine months later on May 26, 2013, declared on the document header: "This is an addendum to the original encounter note dated 9/13/2012. It serves to further clarify and detail the **diagnosis and conditions that existed at the time of this visit**. These diagnosis [sic] coexisted and required or affected the care, treatment, or management of [Patient] at the time of this encounter." Ex. M (emphasis in original). The form then suggested several conditions for the provider to check off as coexisting and requiring or affecting the care, treatment, or management of the patient at the time of the encounter. *Id.*

368. DxID's MRA form highlights in bold the phrase "**the diagnosis and conditions that existed at the time of the visit**," which indicated that DxID was not merely asking but rather asserting as facts that the identified conditions existed during the service year encounter. Moreover, the form goes on to state, unequivocally, that the conditions listed on the form "coexisted and required or affected the care, treatment, or management of [the patient] at the time of this encounter."

369. But Gaffney, DxID, and IH all understood that the conditions listed on the forms often did not reflect a patient's actual medical conditions or indication on medical records. As Gaffney had told GHC's Sather with respect to conditions listed on MRA forms, "some will be correct, some not correct." They also knew that the conditions were often added as a result of DxID's algorithm or based on Gaffney's uninformed belief that everyone over 70 has kidney disease.

370. DxID and IH knew or recklessly disregarded the fact that the diagnosis codes captured and submitted because of the addenda process often did not coexist at the time of the patient encounter in the relevant DOS year and/or were not documented during an encounter in the DOS year as requiring or affecting patient care, treatment, or management.

371. As far back as 2009, IH was aware that similar practices used by Cognisight were suspect. On November 25, 2009, when IH was using Cognisight as its risk adjustment vendor, Gaffney sent an email to Tracy and others at IH admitting a significant error in a query form. An OBGYN who had treated her patient for years had complained to IH about receiving an "addendum . . . asking her to confirm that the member had a history of prostate cancer." Gaffney admitted that prostate cancer was listed on the female patient's addendum

automatically because "when a married couple has any disease, both were assigned to that disease."

372. Gaffney, DxID, and IH were also aware that providers spent little time reviewing the MRA forms, and instead accepted DxID's representation that the conditions existed. Gaffney told IH's Faso on November 3, 2011 that providers "don't really read all the information we send them regarding the forms." Gaffney also told GHC's Sather on May 30, 2012, that it only took 2 or 3 minutes for providers to review and complete the MRA forms.

373. Similarly, on August 4, 2014, IH Coding Integrity Manager Leah Mateczun described problems inherent in DxID's addenda process to IH employees, including Tracy and IH's Internal Audit Manager, George Wands. Among the issues Mateczun identified was that providers were relying on IH for the underlying review of medical records for substantiating conditions in the addenda. As Mateczun explained: "We have been told at the offices that typically the physicians do not review the records and most times try to remember by memory if their patients have the conditions or not."

374. IH employees understood this posed a significant risk of submitting inaccurate diagnosis codes. As Tracy acknowledged: "So they are trusting that the info we are giving them is enough for them to sign off. That is the risk point of us doing this for them."

375. While Defendants knew that providers seldom reviewed the addenda and spent only two to three minutes when they did, Defendants also knew or recklessly disregarded the fact that providers did not have additional records or information that was not already available to Defendants. As such, Defendants were functionally asking providers to confirm from memory serious diagnoses that Defendants asserted as true and coexisting, although Defendants knew that "some will be correct, some not correct."

376. IH was not simply aware that providers were not reviewing medical records, it was also aware that providers were not updating their own files to reflect the newly captured diagnoses, despite the MRA forms requiring providers to "affirm" that the addenda "will be placed in the patient's medical record." In meeting notes circulated on August 28, 2013, to several IH personnel, including Tracy and Mateczun, a section concerning "DXiD Addendums" reported that "Doctors are signing the DXiD addendums but not updating the medical record diagnosis list."

377. The failure of providers to update the medical records suggests that they did not consider these conditions to have affected treatment in the relevant DOS year and that diagnosis codes submitted based on the addenda were not properly documented in medical records for risk-adjustment purposes.

378. Indeed, IH was concerned enough about the addenda process that it temporarily stopped using DxID for a few months 2015. Tracy testified that the reason for temporarily stopping DxID's work was directly related to concerns about the use of addenda. Those concerns ultimately did not dissuade IH from continuing to use DxID, as IH restarted DxID's chart review program, including the addenda process, in 2016.

379. In the end, DxID captured, and IH submitted, diagnosis codes supported solely by impermissibly leading addenda for DOS years 2010 through at least 2017, despite knowing that providers undertook, at best, a perfunctory review of the MRA forms before signing and returning them.

iii. DxID and IH relied on late or untimely MRA forms.

380. In addition to leading providers to include new diagnoses in the beneficiaries' medical records, Defendants ignored CMS guidance that "Addenda/Amendments to medical records must be made in a timely manner. For purposes of validation, changes or updates to medical records are typically made within 60 (and typically 30) days of a face-to-face visit." *See* CMS, *Calendar Year 2005 Medicare Advantage Risk Adjustment Data Validation Frequently Asked Questions* (Aug. 17, 2006).

381. The importance and reliability of timely addenda is well-understood in the healthcare industry. With respect to the use of addenda, AHIMA instructed MAOs that "[t]he more time that passes the less reliable the entry becomes." AHIMA, *Maintaining a Legally Sound Health Record: Paper and Electronic* (2015). As such, AHIMA counseled that addenda should be timely and should include the date of and reason for the addition. *See* AHIMA, *Amendments, Corrections, and Deletions in the Electronic Health Record Took Kit* (2015).

382. As alleged above, providers did not necessarily possess additional documentary information about patient encounters to refresh their recollection and were simply being required to confirm serious diagnoses from memory and from conclusory assertions by DxID that the condition coexisted during the patient encounter.

383. Nonetheless, it was DxID's policy to use addenda up to a year after the date of service. True to its policy, DxID regularly sent addenda to providers many months after the date of service, and IH relied on these outdated addenda to support new diagnosis code submissions.

384. Gaffney falsely claimed that a 12-month look-back period was "conservative." As she explained in a September 6, 2011, email, using a longer look back for addenda was a

way to achieve "an increase in recoveries" and that "[t]he choice of 12 months is somewhat arbitrary . . . ."

385. Despite her assurances that the DxID was being conservative, Gaffney, DxID, and IH knew or recklessly disregarded that seeking such late addenda as means to retroactively bolster the medical record caused the submission of diagnosis codes that were not supported by documentation in the medical records as relevant to patient care during an encounter in the DOS year.

386. DxID and Gaffney were on notice about the unreliability of their late addenda process. They were aware that part of the reason that GHC refused to use DxID's addenda process was due to concern that applying a 12-month look back was impermissible.

387. In May of 2012, when Gaffney tried to persuade GHC to use late addenda for DOS year 2011 charts, Sather asked Gaffney for support for her position that it was permissible to use addenda that were obtained up to 12 months after the date of service, and Sather specifically pointed Gaffney to CMS guidance that prohibited late addenda.

388. Gaffney responded that she "would like to get a legal opinion and/or high level expert opinion to support or deny what we have discerned related to the late entries and correction," but insisted that she "can assure" Sather that DxID and IH had "researched this subject very thoroughly" and "ultimately, [IH] w[as] comfortable with the information they researched and legal opinions they gathered." *Id.* She concluded, "we are on pretty solid ground."

389. When her personal assurances were not enough for GHC, Gaffney sent Sather advice she obtained from the law firm. But even according to the information Gaffney provided, her approach was suspect. Gaffney wrote Sather: "Individuals at CMS (not binding

on the agency) may believe a reasonableness test should be applied to the length of time after a face-to-face visit that a new diagnosis should be coded for RAPS, which might be 90 days, but there is no formal guidance as to how they would be treated on appeal."

390. Although Gaffney was aware that regulators viewed look backs longer than 90 days to be unreasonably distant from the patient encounter and that providers cannot be reasonably expected to recall from memory patient encounters months later, Gaffney claimed that there was no formal rule and that the absence allowed DxID to seek addenda from as far back as it wanted without regard for the reliability of the information.

391. Gaffney, DxID, and IH were not only on notice that a 12-month look back was unacceptable because of GHC's questions and decision to forego the addenda process, but there was also internal dissension within IH about the time limits for addenda.

392. IH employees questioned DxID's use of a 12-month timeframe for submitting addenda and identified information directly from CMS indicating that such a timeframe could be considered fraudulent and would likely lead to the submission of inappropriately documented diagnosis codes. On May 8, 2012, Spagna emailed Faso about the addenda program and attached documentation from CMS and AHIMA explaining the need for addenda to be "timely and bear the current date and reason for the addition or clarification of information being added to the medical record." *See also CMS Medicare B News,* Issue 207 (Oct. 14, 2003); AHIMA*, Amendments, Corrections and Deletions in the Electronic Health Record Toolkit* (2009).

393. Indeed, there was a clear understanding among Gaffney and IH employees that addenda over 90 days old were suspect. On June 29, 2012, for instance, Gaffney sent an email to IH employees, including Tracy and Faso, explaining: "We do know that CMS would like

to apply a 90-day post visit rule to the addendum submission but that they will not and have not published any guidance in this regard."

394. The concerns within IH did not abate, however. In January 2013, Mateczun pointed Tracy to a transcript of a call with CMS in which timeframes for addenda were discussed. The transcript, from a December 5, 2011 call, involved a question regarding the timeframe for when an addendum or late entry could be added. Melanie Combs-Dyer, a Senior Advisor at CMS, responded by directing the questions to the program integrity manual and explaining that a late entry "is more than a few days, you know, if you're talking about months after the fact, the delayed documents of late entries made to the medical record, we instruct our contractors to refer those to the fraud department." She went on to explain that "people who remember, you know, six months after the fact, that they did something during an exam perhaps aren't remembering correctly."

395. In the same transcript, which Mateczun had sent Tracy, a CMS physician elaborated: "The further that it gets away from the date of service or the date of that original note, the less weight is tend [sic] to be given that, because of recall issues and other complicating factors. So, you know, an addendum to an office visit, recalled four months later is obviously more suspect than a note that may be made within, as Melanie says, a day or two after the initial office visit."

396. Although the discussion captured in the transcript may have been more directly related to FFS programs, it nevertheless reflected the prevailing view on the suspect nature of late addenda and Defendants' knowledge that their practice was viewed as potentially fraudulent by CMS.

397. Again, despite these warnings that late addenda are inherently unreliable, and that corrections made months later are untimely, Tracy and IH continued to follow Gaffney's advice that IH could submit addenda as far back as they wanted without regard for the reliability of the added diagnosis codes—which, as discussed above, were being suggested to providers who, as Gaffney understood, spent little time reviewing the MRA forms.

398. Indeed, Tracy explained that IH relied solely on DxID's position with respect to the use of late addenda.

399. Not only did IH ignore its obligation to further inform itself of the rules regarding proper use of addenda, but it ignored other red flags. In June 2013, IH received the results of an audit conducted by HealthRisk Partners ("HRP"). Of 22 charts reviewed, "HRP failed 15 instances or 68%."[33] Specifically, "35 HCCs that were not substantiated," and "approximately half of the records had medical record 'addendums' obtained by another coding vendor for the purpose of HCC validation," referring to DxID. Ex. N at 4.

400. The audit result went on to state that "HRP's Vice President of Clinical Coding Services and CEO reviewed the addendums and do not believe that they are acceptable for Risk Adjustment purposes. Further, HRP believes they are expressly prohibited under RADV coding rules and, in the event of an actual RADV audit, HRP would not submit these documents to CMS." Ex. N at 4.

401. On April 1, 2015, Mateczun again expressed her concern about the DxID addenda process. She emailed Tracy and noted that "[t]here is one HCC that has ONLY been

[33] Eight of fifteen failures were "due to coding Chronic Kidney Disease directly from lab values where the physician did not diagnose this condition. Coding from lab values is not allowed by CMS or national coding standards." Six "errors were related to incorrect ICD9 coding. One coding error was related to a missing chart." Ex. N at 4.

reported by DxID through the addendum process. I just wanted to make sure that you were ok with me submitting this date of service to CMS? While I am not comfortable with it, I think this may help to solve the age-old question as to whether an addendum will pass a RAD-V." In response, Tracy wrote: "OH boy. I think I need to let other[s] know this. If that is all we have to support it, then that's what we have to send."

402. Although Defendants were aware that addenda submitted months after the patient encounter were inherently unreliable, that providers reviewed addenda cursorily or not at all, that some conditions listed on the MRA forms were incorrect, and that other MAOs and industry participants would not submit diagnosis codes based on such practices, they ignored these concerns and submitted diagnosis codes based on DxID's addenda process anyway.

403. For DOS years 2010 through 2017, IH submitted codes from at least:

a. 14,551 addenda between 120 and 180 days after the date of service;

b. 37,895 addenda between 180 and 240 days after the date of service;

c. 36,077 addenda between 240 and 300 days after the date of service;

d. 31,265 addenda between 300 and 360 days after the date of service; and

e. 5,080 addenda that were more than 360 days after the date of service.

iv. IH continued using DxID's addenda process because it was too profitable to abandon.

404. Despite knowing that that DxID's addenda policy did not comport with prevailing guidance and that DxID's actual addenda practice resulted in the submission of diagnosis codes that lacked documentation in the medical record evidencing the condition's relevance to patient care during an encounter in the DOS year, IH relied on it because of the

tremendous value it provided. As Gaffney told GHC's Sather in 2012, the addenda process represented about 50 percent of the recoveries from DxID's services.

405. Haughton would make this same point to IH in 2015 when IH was considering a new chart review vendor.

406. In or about 2015, Tracy and the IH Medicare team introduced another chart review vendor to IH. Among the reasons for exploring a new vendor, according to Tracy, was that IH was concerned about DxID's use of addenda.

407. Haughton intervened to ensure that DxID remained the sole chart review vendor at IH by lobbying Faso and members of IH's Internal Audit Department. Specifically, Haughton argued that the addenda process accounted for half of the revenue that DxID recovered for IH.

408. When that did not stop discussion of hiring a new vendor, Haughton escalated the issue to the IH Board, which resulted in a presentation by Gaffney to the IH Board in which she specifically sought approval to continue to use the addenda process.

409. Tracy's suggestion to use another vendor was overruled and DxID was permitted to proceed with the addenda process at IH.

410. Despite the myriad of warnings and concerns about DxID's addenda process, IH relied on the program to "capture" new and valuable diagnosis codes that were not based on underlying medical records.

411. IH submitted 126,182 addenda to CMS to support thousands of additional diagnosis codes for DOS years 2010 through at least 2017.

412. IH discontinued using DxID's addenda process entirely in 2019.

FIRST CLAIM FOR RELIEF

False Claims Act: Presentation of False or Fraudulent Claims
31 U.S.C. § 3729 (a)(1)(A)

413. The United States repeats and re-alleges the allegations contained in Paragraphs 1 to 412 above as though they are fully set forth herein.

414. Defendants IHA, IHC, DxID, and Gaffney violated 31 U.S.C. § 3729(a)(1)(A) by knowingly presenting and causing the presentment of false or fraudulent claims for payment or approval resulting in inflated Medicare reimbursements to which they were not entitled.

415. Had CMS been aware of Defendants' knowing false coding, it would have refused to make risk-adjustment payments based on the false coding and/or pursued other legal remedies to avoid the potential disruption of MA Plan benefits to thousands of Medicare beneficiaries for whom Defendants provided healthcare services and/or insurance. CMS has now done so via this suit that it has authorized.

416. By virtue of the said false or fraudulent claims, the United States has incurred damages and, therefore, is entitled to treble damages under the FCA, plus a civil penalty for each violation of the Act.

SECOND CLAIM FOR RELIEF

False Claims Act: Making or Using False Records or Statements
31 U.S.C. § 3729 (a)(1)(B)

417. The United States repeats and re-alleges the allegations contained in Paragraphs 1 to 416 above as though they are fully set forth herein.

418. Defendants IHA, IHC, DxID, and Gaffney violated 31 U.S.C. § 3729(a)(1)(B) by knowingly making, using, and causing to be made or used, false records and statements

material to false or fraudulent claims resulting in inflated Medicare reimbursements to which they were not entitled.

419. Had CMS been aware of Defendants' knowing false coding, it would have refused to make risk-adjustment payments based on the false coding and/or pursued other legal remedies to avoid the potential disruption of MA Plan benefits to thousands of Medicare beneficiaries for whom Defendants provided healthcare services and/or insurance. CMS has now done so via this suit that it has authorized.

420. By virtue of the said false records and statements, the United States has incurred damages and, therefore, is entitled to treble damages under the FCA, plus a civil penalty of each violation of the Act.

THIRD CLAIM FOR RELIEF

False Claims Act: Reverse False Claims 31 U.S.C. § 3729 (a)(1)(G)

421. The United States repeats and re-alleges the allegations contained in Paragraphs 1 to 420 above as though they are fully set forth herein.

422. Defendants IHA, IHC, DxID, and Gaffney violated the first part of 31 U.S.C. § 3729(a)(1)(G) by knowingly making, using, and/or causing to be made or used false records and statements material to an obligation to pay or transmit money or property to the Government by creating false records and making false statements relating to their failure to delete codes for unsupported diagnoses or to repay CMS overpayments to which they were not entitled.

423. Had CMS been aware of Defendants' knowing false coding and knowing failure to delete codes for unsupported diagnoses or to return overpayments, it would have taken steps to recover them. CMS has now done so via this suit that it has authorized.

424. By virtue of the said false records, statements, and other acts of concealment and improper avoidance, the United States has incurred damages and, therefore, is entitled to treble damages under the FCA, plus a civil penalty for each violation of the Act.

FOURTH CLAIM FOR RELIEF

False Claims Act: Reverse False Claims 31 U.S.C. § 3729 (a)(1)(G)

425. The United States repeats and re-alleges the allegations contained in Paragraphs 1 to 424 above as though they are fully set forth herein.

426. Defendants IHA, IHC, DxID, and Gaffney violated the second part of 31 U.S.C. § 3729(a) (1)(G) by knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the Government by failing to delete codes for unsupported diagnoses or otherwise repay CMS for overpayments to which they were not entitled.

427. Had CMS been aware of Defendants' knowing false coding, knowing failure to delete codes for unsupported diagnoses, and/or knowing failure to return overpayments, it would have taken steps to recover them. CMS has now done so via this suit that it has authorized.

428. By virtue of the said acts of concealment and/or improper avoidance, the United States has incurred damages and, therefore, is entitled to treble damages under the FCA, plus a civil penalty for each violation of the Act.

FIFTH CLAIM FOR RELIEF

False Claims Act: Conspiracy to Violate the FCA
31 U.S.C. § 3729 (a)(1)(C)

429. The United States repeats and re-alleges the allegations contained in Paragraphs 1 to 428 above as though they are fully set forth herein.

430. Defendants IHA, IHC, DxID, and Gaffney violated 31 U.S.C. § 3729(a)(1)(C) by conspiring to violate 31 U.S.C. § 3729(a)(1)(A), (B), and/or (G).

431. Had CMS been aware of Defendants' conspiracy to submit unsupported codes, it would have refused to make risk-adjusted payments based on the false coding and/or pursued other legal remedies to avoid the potential disruption of MA Plan benefits to thousands of Medicare beneficiaries for whom Defendants provided healthcare services and/or insurance. CMS has now done so via this suit that it has authorized.

432. By virtue of the said conspiracy to submit unsupported codes, the United States has incurred damages and, therefore, is entitled to treble damages under the FCA, plus a civil penalty of each violation of the Act.

SIXTH CLAIM FOR RELIEF

Payment by Mistake

433. The United States repeats and re-alleges the allegations contained in Paragraphs 1 to 432 above as though they are fully set forth herein.

434. As a consequence of Defendants' misconduct and the acts set forth above, IHA, IHC, DxID, and Gaffney received monies from the United States as a result of a mistaken understanding. Specifically, the United States reimbursed GHC and IHA, who in turn paid IHC, DxID, and/or Gaffney, under the mistaken understanding of the United States that

such claims were based on valid risk-adjustment diagnoses. Had the United States known the truth, it would not have paid such claims. Payment was therefore by mistake.

435. As a result of such mistaken payments, the United States has sustained damages for which IHA, IHC, DxID, and Gaffney are liable in an amount to be determined at trial.

SEVENTH CLAIM FOR RELIEF

Unjust Enrichment

436. The United States repeats and re-alleges the allegations contained in Paragraphs 1 to 435 above as though they are fully set forth herein.

437. As a consequence of Defendants' conduct and the acts set forth above, IHA, IHC, DxID, and Gaffney were unjustly enriched at the expense of the United States. In equity and good conscience such money belongs to the United States.

438. The United States is entitled to recover such money based on Defendants' unjust enrichment in an amount to be determined at trial.

PRAYER

WHEREFORE, the United States requests that judgment be entered in its favor and against Defendants, IHA, IHC, DxID, and Gaffney, as follows:

On Claims I, II, III, IV, and V (False Claims Act), against all Defendants jointly and severally, for: (i) the amount of the United States' damages, trebled as required by law; (ii) the maximum civil penalties allowed by law, (iii) the costs of this action, plus interest as provided by law, and (iv) any other relief that this Court deems appropriate.

As to Claim VI (Payment Under Mistake of Fact), for: (i) an amount equal to the money paid by the United States through the Medicare Advantage Program as a result of

Defendants' false submissions, plus interest; (ii) the costs of this action, plus interest, as provided by law; and (iii) any other relief that this Court deems appropriate.

As to Claim VII (Unjust Enrichment), for: (i) an amount equal to how much Defendants were unjustly enriched, plus interest; (ii) the costs of this action, plus interest, as provided by law; and (iii) any other relief that this Court deems appropriate.

DEMAND FOR JURY TRIAL

The United States of America hereby demands a trial by jury.

DATED: September 13, 2021

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