

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA
ex rel. **SUZANNE CRAWFORD,**

Plaintiffs/Relator,

-v-

INDEPENDENCE BLUE CROSS,

Defendant.

) **Case No.** _____

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) **COMPLAINT AND JURY DEMAND**

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) **TO BE FILED IN CAMERA AND UNDER**

) **SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)**

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The Relator, Ms. Suzanne Crawford (“Relator” or “Ms. Crawford”), by and through the undersigned counsel, and on behalf of the United States (the “Government”) alleges as follows:

I. INTRODUCTION

1. This is a *qui tam* action by Ms. Crawford against Independence Blue Cross (“IBC”). IBC is the largest health insurer in the Philadelphia area, serving more than three million people in the region and more than eight million people nationwide.¹

2. This case is simple and the fraud alleged herein is straightforward. Federal law requires that when a Medicare Advantage Organization (“MAO”)—like IBC—conducts a retrospective chart review of its Medicare beneficiaries’ entire medical record in order to identify and submit additional diagnosis codes to increase Medicare Advantage payments, it must also locate and delete inaccurate diagnosis codes. Simply put, a MAO chart review cannot only do “additions” without also doing “deletions”—both are required. Doing only the former, without also doing the latter, results in a one-way “code harvesting program” that is wrong, illegal, and a

¹ *About Independence Blue Cross*, INDEPENDENCE BLUE CROSS, available at <https://www.ibx.com/about-us/our-company> (last visited Nov. 3, 2020).

violation of the False Claims Act. Indeed, several MAOs have been recently prosecuted for such fraud.²

3. Here, from 2013 to 2016 and, upon information and belief, continuing to the present day (the “Relevant Period”), IBC implemented three separate retrospective code harvesting programs (outlined below) designed to identify and submit additional diagnosis codes and increase Medicare Advantage payments, but which intentionally ignored—and failed to delete—inaccurate codes. In doing so, IBC knowingly disregarded its duty to ensure the accuracy of the risk adjustment diagnosis data that it submitted to the Centers for Medicare and Medicaid Services (“CMS”) for thousands of Medicare beneficiaries covered by the Medicare Part C plans operated by IBC. By ignoring its duty to delete thousands of inaccurate diagnoses, IBC unlawfully obtained and retained tens of millions of dollars in payments under the risk adjustment payment system for Medicare Part C, in violation of the False Claims Act.

4. As a MAO, IBC is responsible for covering the cost of services rendered by healthcare providers like hospitals and doctors’ offices for the Medicare beneficiaries enrolled in IBC’s Part C plans. IBC, in turn, received monthly capitated payments from CMS for providing such coverage. The payments received by IBC were based directly on diagnosis data IBC submitted to CMS in the form of ICD diagnosis codes. IBC knew that, because the diagnosis codes it submitted to CMS affected payment directly, it had an obligation to ensure that its data submissions were accurate and truthful, including by complying with the ICD coding guidelines adopted by CMS regulations.

² *United States v. Anthem, Inc.*, No. 1:20-cv-2593 (S.D.N.Y. 2020); *see also United States ex rel. Sewell v. Freedom Health, Inc.*, Case No. 8:09-cv-1625 (M.D. Fla. 2017); *United States ex rel. Swoben v. Secure Horizons, et al.*, Case No. 2:09-cv-05013 (C.D. Cal. 2009).

5. In direct violation of IBC's obligations to submit accurate and truthful data submissions and to comply with CMS coding guidelines, IBC implemented three separate retrospective code harvesting programs intended to identify and submit additional diagnosis codes to increase Medicare Advantage payments, but that failed to locate and delete inaccurate diagnosis codes. Simply put, IBC's code harvesting programs only did "additions" and did not do "deletions"—even though both are required by law.

6. The first program—called the "CARA Program," (*i.e.*, Capitated Risk Adjustment Process Program)—was performed by IBC's third-party Vendor, Inovalon. The second program—called the "IBX Review"—was performed internally by IBC and entailed IBC personnel reviewing a full year's worth of Medicare beneficiaries' medical records for additional codes. The third program—called the EMR Data Exchange Program (*i.e.*, Electronic Medical Records Data Exchange Program)—was performed internally by IBC using data extracted from its providers' EMR system.

7. All of these programs were "retrospective" because they typically occurred several months after IBC had submitted to CMS the diagnosis codes reported by providers.³ These code harvesting programs were in-depth and expansive, and were specifically designed to identify all additional diagnosis codes that could be supported by the records, without also looking for and deleting inaccurate diagnosis codes.

8. The sole purpose of these three code harvesting programs was to increase revenue by submitting additional diagnosis codes to CMS, while intentionally ignoring—and failing to delete—inaccurate codes that could not be substantiated by the medical records. IBC knew that

³ Upon information and belief, the CARA Program was fully replaced by the IBX Review program in 2016, with the IBX Review program continuing to the present day.

the results of its programs could indicate whether the diagnosis codes IBC previously submitted to CMS were accurate. Indeed, IBC regularly conducted sample audits of its CMS submissions that identified inaccurate submissions, and therefore knew that other codes it had previously submitted to CMS, but which could not be substantiated by IBC's retrospective code harvesting programs, had likely been reported inaccurately. Yet IBC knowingly and intentionally failed to delete the inaccurate codes submitted to the Government.

9. While IBC could have readily written a computer algorithm to find inaccurately reported diagnosis codes by comparing previously-submitted codes against program results, IBC made no effort to do so during the Relevant Period. IBC viewed its code harvesting programs solely as a means to identify and generate new diagnosis codes for it to obtain higher Medicare payments. Indeed, finding and deleting inaccurate diagnosis codes would have reduced IBC's revenue from Medicare. And the additional Medicare revenue IBC received as a result of its retrospective code harvesting programs was significant. For example, while IBC spent \$6 million on its CARA Program to review Medicare beneficiaries' charts, IBC's total 2015 Medicare Revenue generated by the CARA Program alone was ***\$23.1 million***, equaling a 2015 Medicare ***return on investment of 3.85 to 1***. (See *infra* Section VI.)

10. Simply put, these code harvesting programs were specifically designed to increase Medicare revenue in violation of the applicable CMS rules and regulations. As a result of these programs, IBC received tens of millions of dollars in additional Medicare revenue it otherwise would not have received, while willfully ignoring and recklessly disregarding its duty to identify and delete inaccurate codes in its CMS submissions that IBC, based on known audit results, IBC knew were likely to exist.

11. Ultimately, the extraordinary profits IBC obtained through its one-sided code harvesting programs came at the expense of the Government. By knowingly disregarding its regulatory and contractual obligations to correct—and delete—inaccuracies in its diagnosis data submissions, IBC improperly obtained or retained millions of dollars from the Government in violation of the False Claims Act. Upon information and belief, Relator estimates that IBC's one-sided code harvesting programs (*i.e.*, focusing solely on finding additional codes to submit to CMS without also identifying and deleting inaccurate codes) generated ***\$20 million or more per year in additional revenue for IBC.***

12. Ms. Crawford was employed at IBC from September 2013 to November 2016, where she worked in the Informatics department as an analyst, manager, and eventually Director of IBC's Risk Adjustment Business Processes. In those roles, she helped develop and manage IBC's retrospective code harvesting programs, and was responsible for overseeing the development of software and processes to identify and retrieve diagnosis codes for submission to the Government. She has firsthand knowledge that IBC's supplemental programs focused solely on finding additional codes to submit, while willfully ignoring and failing to delete inaccurate codes. Ms. Crawford discerned the fraudulent nature of IBC's one-sided programs after leaving IBC and becoming employed at another MAO in the industry, and is now taking steps to report the years' long fraud to the Government.

13. Under the terms of the False Claims Act, this Complaint is to be filed *in camera* and under seal and is to remain under seal for a period of at least 60 days and shall not be served on Defendant until the Court so orders. The Government may elect to intervene and proceed with the action within the 60-day time frame, or within any extensions of that initial sixty-day period

granted by the Court for good cause shown, after it receives both the Complaint and the Material Evidence submitted to it.

II. NATURE OF THE ACTION

14. This is an action to recover treble damages and civil penalties under the False Claims Act, 31 U.S.C. §§ 3729-3733.

15. Under the False Claims Act, a private person may bring an action in federal district court for herself and for the United States, and may share in any recovery. 31 U.S.C. § 3730(b). That private person is known as a “Relator” and the action that the Relator brings is called a *qui tam* action.

III. JURISDICTION AND VENUE

16. This Court has subject matter jurisdiction to adjudicate this action under 28 U.S.C. §§ 1331 and 1345.

17. This Court has personal jurisdiction over IBC pursuant to 31 U.S.C. § 3732(a) because IBC transacts and has transacted business in this District.

18. Venue is proper in this District under 28 U.S.C. § 1391(b)-(c) and 31 U.S.C. § 3732 because a substantial part of the events or omissions giving rise to the claims occurred in this District and IBC transacted business in this District.

IV. THE PARTIES

19. Ms. Crawford brings this action on behalf of the United States, including its agency, the Department of Health and Human Services (“HHS”), and its component, the Centers for Medicare & Medicaid Services (formerly the Health Care Financing Administration (“HCFA”)), and all other applicable government healthcare programs, such as Amerigroup, TRICARE/CHAMPUS, Blue Cross/Blue Shield – CHIP, and Veterans Administration (“VA”).

20. Ms. Crawford also brings this action on behalf of herself, as permitted under the False Claims Act. Ms. Crawford is a citizen of the United States and a resident of the Commonwealth of Pennsylvania. Ms. Crawford was responsible for overseeing the development of software and processes that would identify suspects for chart review and has direct and independent knowledge of the information on which the allegations in this Complaint are based. Ms. Crawford is the original source of these allegations and has knowledge of the false claims and records that IBC knowingly, falsely, and fraudulently submitted to the Government as alleged herein.

21. Defendant Independence Blue Cross is a Pennsylvania insurance company headquartered in Philadelphia, Pennsylvania. As part of its lines of business, IBC operates as a Medicare Advantage Organization and offers various Medicare Advantage plans to Medicare beneficiaries, receiving hundreds of millions of dollars in payments from Medicare.

V. LEGAL FRAMEWORK

A. The False Claims Act

22. The False Claims Act (“FCA”) provides, in pertinent part, that any person who:

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

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

...

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

is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, . . . plus 3 times the

amount of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729(a).

23. The Affordable Care Act requires a person who has received an overpayment of Medicare or Medicaid to report and return the overpayment within 60 days of identification or the date any corresponding cost report is due, and failure to report and return the overpayment is an obligation for the purposes of the False Claims Act under 31 U.S.C. § 3729(a)(1)(G). *See* 42 U.S.C. § 1320a-7k(d).

24. For purposes of the FCA:

(1) the terms “knowing” and “knowingly”

(A) mean that a person, with respect to information – (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information; and

(B) require no proof of specific intent to defraud.

31 U.S.C. § 3729(b).

25. Effective November 2, 2015 (the date of enactment of the Federal Civil Penalties Inflation Adjustment Act, Improvements Act of 2015, Public Law 114-74, sec. 701 (“2015 Amendments”)), the civil penalties for FCA violations increased from a minimum-maximum per-claim penalty of \$5,500 and \$11,000 to \$10,781 and \$21,563. The increased amounts apply to civil penalties assessed for violations occurring after November 2, 2015. Violations that occurred on or before November 2, 2015 are subject to the previous penalty amounts. On February 3, 2016, pursuant to the 2015 Amendments annual re-indexing of the FCA penalties for inflation, the civil penalties again increased to a minimum-maximum per-claim penalty of \$10,957 and \$21,916. On January 19, 2018, the FCA penalties were again increased to a minimum-maximum per-claim penalty of \$11,181 and \$22,363. In February 2019, the amounts were increased again to \$11,463

and \$22,927. 84 Fed. Reg. 2445, 2446 (Feb. 7, 2019). In January 2020, these amounts were again increased to \$11,665 and \$23,331. 15 C.F.R. § 6.3 (2020); 85 Fed. Reg. 207, 208 (Jan. 3, 2020).

B. The Medicare Advantage Program and Its Risk Adjustment Payment System

1. Medicare Advantage and the Role of Part C MAOs

26. 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 *et seq.*

27. Parts A and B of the Medicare Program are commonly known as “traditional” Medicare. Part A covers inpatient and institutional care, while Part B covers physician, hospital, outpatient, and ancillary services and durable medical equipment. Under Medicare Parts A and B, CMS reimburses healthcare providers (*e.g.*, hospitals and physicians’ offices) directly using a fee-for-service system. Specifically, healthcare providers submit claims to CMS for medical services actually rendered. CMS, in turn, pays the providers directly for each service based on payment rates established by the Government.

28. On the other hand, Medicare Part C—which is at issue in this case—involves Medicare beneficiaries who have elected to receive Part A and Part B benefits through a Medicare Advantage plan (“Part C Plan” or “MA Plan”). *See* 42 U.S.C. §§ 1395w-21 to 1395w-28. The MA Plans, in turn, are operated and managed by MAOs, which are private insurers like IBC. *See* 42 C.F.R. §§ 422.2, 422.503(b)(2).

29. Under Medicare Part C, beneficiaries receive healthcare services managed by those plans. More specifically, when a healthcare provider furnishes medical services to a Medicare beneficiary enrolled in an MA Plan, the provider submits claims and encounter data to the MAO that operates the MA plan in order to receive payment from the MAO, instead of CMS.

30. Congress expressly delegated authority to CMS to issue rules to implement and regulate Medicare Part C. *See* 42 U.S.C. § 1395w-26(b). Pursuant to that delegation, CMS has promulgated regulations that, *inter alia*, define the MAOs' obligations and responsibilities. *See generally* 42 C.F.R. Part 422. As discussed more fully below, CMS's Part C regulations prohibit IBC from performing one-way code harvesting programs.

2. Medicare Part C's Risk Adjustment Payment System and the Role of ICD and HCC Codes in CMS's Calculation of Risk Adjustment Payments

31. A central and distinguishing feature of Medicare Part C is how CMS determines the amount of payments that each MAO is entitled to receive for providing healthcare coverage to beneficiaries enrolled in one of the MAO's Part C plans. Instead of compensating a MAO on a fee-for-service basis for specific medical services provided to a beneficiary, CMS makes monthly payments to the MAO in a fixed, capitated (per beneficiary enrollee in each Part C plan) amount for providing coverage for each of Medicare beneficiary enrolled in the Part C plan.

32. Unlike under Parts A and B, the per-member, per-month payments that CMS makes to MAOs under Medicare Part C do not depend on the amount of services provided to a specific beneficiary. Instead, the capitated rate is determined based on how the bid submitted by a 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.

33. Within this system, which Congress has mandated since 2000, *see* 42 U.S.C. § 1395w-23(a)(1)(C) (directing CMS to adjust the capitated payments for each MA Plan enrollee based on each enrollee's demographic factors and health status), CMS uses its risk adjustment

payment system to determine the capitated payments based on the expected risk of each beneficiary.⁴

34. Specifically, CMS calculates, for each beneficiary enrolled in a Part C Plan, a risk score—also known as the risk adjustment factor or “RAF”—which acts as a multiplier for purposes of determining the capitated payment for that enrollee. *See* 42 C.F.R. § 422.308(e).⁵ In other words, CMS pays MAOs more for beneficiaries with certain serious illnesses or chronic medical conditions and, thus, higher risk scores, than for beneficiaries without those conditions and, thus, lower risk scores.

35. Since 2004, CMS has employed a hierarchical condition category (“HCC”) model to calculate the risk score for Medicare beneficiaries enrolled in Part C Plans. As directed by Congress, the HCC model considers both demographic factors and the health status of Medicare beneficiaries. *See* 42 C.F.R. § 422.2.

36. Clinically, HCCs are categories of related medical diagnoses including major, severe, and/or chronic illnesses. *See id.* Between 2004 and 2013, there were 70 HCCs in CMS’s Part C risk adjustment model. Starting in 2014, and after CMS revised its model, the number of HCCs increased to 79.

⁴ Because CMS calculates and makes the monthly capitated payments to MAOs in a given payment year before CMS necessarily has received all the diagnosis data relevant to the risk-adjustment calculation, CMS also engages in a “reconciliation process” after the conclusion of each payment year. *See* 42 C.F.R. § 422.310(g)(2). Through this process, CMS may conclude that “adjustments to payments are necessary” based on subsequently-submitted diagnosis data, which may result in CMS making an additional reconciliation payment to an MAO or seeking a reconciliation refund from the MAO. *See id.*

⁵ To determine the base monthly payment amount for Medicare beneficiaries enrolled in a specific Part C Plan, CMS uses a bidding process in which each Part C Plan, through its MAO, submits a bid amount. That bid is then compared to an administratively set benchmark set by CMS. *See* 42 C.F.R. Part 422, subparts F and G.

37. Each HCC correlates with the marginal predicted cost of medical expenditures for that set of medical conditions based on CMS’s data from administering the traditional Medicare Fee-For-Service program. Some examples of HCC codes are HIV/AIDS (HCC 1), metastatic cancer and leukemia (HCC 8), congestive heart failure (HCC 80), and ischemic stroke (HCC 100).⁶ Higher relative values (also sometimes referred to as relative factors, or coefficients) are assigned to HCCs that include diagnoses with greater disease severity and treatment costs.

38. A single Medicare beneficiary may have none, one, or multiple HCCs, which affect the risk adjustment payment calculated by CMS according to the relative values of those HCCs and the base payment amount for a specific Medicare beneficiary.

39. To determine which HCCs are applicable to each Medicare beneficiary, CMS’s HCC model relies on the diagnoses—more specifically ICD diagnosis codes—documented by medical encounters that Medicare beneficiaries have with authorized healthcare providers (*e.g.*, a visit to a doctor’s office or an inpatient stay at a hospital). Simply put, the ICD diagnosis codes submitted by MAOs are used by CMS to calculate the risk adjustment payment.

40. HHS has adopted the ICD Guidelines for Coding and Reporting as the standard for medical record documentation. *See* 45 C.F.R. § 162.1002(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 coding guidelines. *See* 42 C.F.R. § 422.310(d)(1) (requiring MAOs to submit data in conformity with “all relevant national standards”).

⁶ HCC numerical codes changed between the 2004-2013 model (known as Version 12) and the 2014 model (known as Version 22). The numerical examples of HCC codes cited herein are from the Version 22 model.

41. Practically, the ICD coding and classification system allows healthcare providers, insurance carriers and public health agencies to use alphanumeric codes to represent diagnoses. Each disease, injury, infection and symptom has its own ICD code. During the relevant times, the applicable standards for ICD coding have been set forth in three systems—first, up to October 1, 2015, the International Classification of Diseases, Ninth Revision, Clinical Modification (“ICD-9”); from October 1, 2015 to May 25, 2019, the International Classification of Diseases, Tenth Revision, Clinical Modification (“ICD-10”); and thereafter the International Classification of Diseases, Eleventh Revision, Clinical Modification (“ICD-11”).

42. Finally, the HCC model is prospective, meaning that it relies on risk-adjusting diagnosis codes from dates of service by a provider in one year (the “DOS year” or “date of service year”) to determine payments in the following year (the “payment year”). In other words, CMS calculates the risk score for each Medicare beneficiary enrolled in Part C anew for each payment year based on the ICD codes from medical encounters that occurred in the immediately preceding year. The higher a Part C beneficiary’s risk score, the higher the payments by CMS to the MAO operating that beneficiary’s Part C plan.

3. CMS’s Risk Adjustment Payment Process and Its RAPS and EDPS Risk Adjustment Data Reporting Systems

43. In most cases, the ICD diagnosis codes reported to CMS for risk adjustment purposes originate from healthcare providers who treat Part C beneficiaries. In this scenario, the risk adjustment data is typically generated and reported in five steps.

44. First, based on a face-to-face encounter between a healthcare provider and a Part C beneficiary, the provider (the physician or a nurse) would document the encounter in the beneficiary’s medical records, including the characteristics of the beneficiary’s illnesses or medical conditions. Next, the provider—or, often, a coder working for the provider—would assign

the diagnosis codes reflecting the beneficiary's illnesses or medical conditions in the provider's records for the beneficiary. Third, MAOs like IBC would receive diagnosis codes from the provider. Healthcare providers can transmit diagnosis codes to an MAO when they submit claims for payment from the MAO for treating the beneficiary, in encounter records reporting the services rendered, or by alternative means (for purposes of this Complaint, diagnosis codes reported by providers to MAOs like IBC are referred to as "provider-reported codes"). Fourth, the MAO would in turn submit those diagnosis codes to CMS using the risk adjustment data reporting systems provided by CMS. Finally, CMS maps each beneficiary's diagnosis codes to HCCs and then calculates each beneficiary's risk score to apply to the payment calculation.

45. During the years relevant to this action, CMS utilized two electronic systems for collecting risk adjustment diagnosis data: (1) the Risk Adjustment Processing System ("RAPS"); and (2) the Encounter Data Processing System ("EDPS"). Up to 2014, CMS calculated risk adjustment payments based solely on the RAPS-submitted diagnosis data. Starting in 2015, CMS has calculated risk adjustment payments using a combination of RAPS and EDPS-submitted diagnosis data. The RAPS data submissions (and, after 2015, the EDPS data submissions) were claims for payment from CMS because the reported diagnosis codes factored directly into CMS's risk adjustment calculations.

46. The data that MAOs submit through the RAPS system have several components. For example, the component known as AAA identifies the submitter, while the component known as BBB identifies the MAO. As relevant here, the CCC component contains the Medicare identification number for a particular beneficiary as well as up to ten diagnostic clusters for that beneficiary. Each cluster, in turn, contains the date on which the medical treatment occurred, the

type of provider, a diagnosis code from the medical encounter, and a “Delete Indicator.”⁷ Because each diagnostic cluster includes a distinct diagnosis that can increase a beneficiary’s risk score, each cluster is, for purposes of the FCA, a separate claim for payment.⁸

47. CMS calculates the risk adjustment payments to be made to MAOs in three phases. First, CMS makes an initial calculation based on the diagnosis data reported by MAOs for the 12-month period ending in the June before a given payment year (*e.g.*, diagnosis data from July 2011 through June 2012 for payment year 2013). *See* 42 C.F.R. § 422.310(g) (requiring MAOs to submit such diagnosis data by September). This initial calculation determines the interim monthly payments that CMS makes to MAOs in the first six months of the payment year.

48. Second, CMS recalculates the risk scores for beneficiaries enrolled in a MAO’s plans based on diagnosis data for medical encounters during the year immediately preceding the payment year (*e.g.*, diagnosis data from January and December 2012 for payment 2013). Based on that recalculation, CMS makes retroactive adjustments to payments made in the first half of the payment year and also updates the interim payments for the second half of the payment year.

49. Third, after the payment year ended, CMS provides a further opportunity for MAOs like IBC to submit or correct the diagnosis data. Based on the additional submissions or corrections, CMS recalculates the risk scores again “to determine if adjustments to payments are necessary.” 42 C.F.R. § 422.310(g)(2). If such adjustments are necessary, CMS makes the adjustments as part of the annual reconciliation process to ensure that the final payments to the

⁷ As discussed more fully below, this indicator allows MAOs to correct or withdraw a false cluster by advising CMS to delete the inaccurate diagnosis code in that cluster.

⁸ In the EDPS system, MAOs similarly submit data with several components, known as “loops.” ICD diagnosis codes are among the data that MAOs are required to submit to CMS using EDPS. Further, like the RAPS system, the EDPS system has mechanisms designed for MAOs to notify CMS to delete certain diagnosis codes so that CMS would not use those codes for purposes of calculating risk-adjustment payments.

MAOs are accurate. This may involve CMS making an additional payment to an MAO if the MAO submitted additional diagnosis data by the final submission deadline, or involve CMS seeking recoupment from the MAO if the MAO deleted inaccurate diagnosis codes.

50. As a condition for using the RAPS and EDPS systems to submit risk adjustment diagnosis data to CMS for risk adjustment payments, MAO's must execute Electronic Data Interchange ("EDI") agreements with CMS. In these agreements, IBC and other MAOs expressly agree to assume a number of specific obligations relating to their risk adjustment data submissions, including the obligation to research and correct risk adjustment data discrepancies.

D. CMS Required MAO's to Follow the "Medical Record Documentation" Standard for Part C Risk Adjustment Diagnosis Data Submissions.

51. Because the accuracy and integrity of CMS's calculation of Part C risk adjustment payments depend on the accuracy of the diagnosis codes MAOs submit to CMS, CMS promulgated regulations regarding the coding and medical record documentation standards for risk adjustment diagnosis data. Specifically, CMS requires MAOs to "submit [diagnosis] data that conform to" the ICD coding guidelines. *See* 42 C.F.R. § 422.310(d)(1) (requiring MAOs to submit data in conformity with "all relevant national standards," which, pursuant to 42 C.F.R. § 162.1002(c), included the ICD coding guidelines); accord Medicare Managed Care Manual ("MMC Manual"), Chap. 7, Ex. 30 (Aug. 2004) (instructing MAOs to follow the ICD coding guidelines in submitting diagnosis codes)

52. As relevant here, the ICD coding guidelines consistently provided that "accurate coding cannot be achieved" in the absence of "complete documentation in the medical record." *See, e.g.*, ICD-10-CM Official Guidelines for Coding and Reporting FY 2014 (the "2014 ICD-10 Coding Guidelines") at 1. This coding standard is widely understood by MAOs like IBC, and they commonly refer to it as the risk adjustment "medical record documentation" requirement. Under

this standard, a diagnosis code can be considered accurate and valid for risk adjustment purposes if it is documented in and supported by medical records for a particular encounter between a patient and a healthcare provider. *See* 2014 ICD-10 Coding Guidelines at 112 (“For accurate reporting of ICD-10 [] diagnosis codes, the documentation should describe the patient’s condition, using terminology which includes specific diagnoses, as well as symptoms, problems, or reasons for the encounter”).

53. In addition, the ICD coding guidelines also specified that a diagnosis code should not be applied if a condition is documented in the medical records as only “probable,” “suspected,” “questionable,” one that the provider is trying to “rule out,” or characterized by “other similar terms indicating uncertainty.”

54. CMS has repeatedly provided instructions to MAOs on how to implement the medical record documentation requirement under the ICD coding guidelines. For example, CMS issued public guidance to emphasize to MAOs that they were responsible for submitting “risk adjustment data that are substantiated by the physician or provider’s full medical record,” *see* MMC Manual Chap. 7, § 111.8 (Aug. 2004), and to ensure that “[a]ll diagnosis codes submitted [are] documented in the medical record,” *see* MMC Manual Chap. 7, § 40 (June 2013). Likewise, provisions in the MMC Manual advised MAOs that they should not submit diagnosis codes for risk adjustment purposes if the condition at issue was only probable or suspected, or questionable. *See* MMC Manual Chap. 7, Ex. 30 (Aug. 2004).

E. CMS Required MAOs to Delete Diagnosis Codes That Were Not Supported by Medical Record Documentation

55. CMS recognized that MAOs may subsequently obtain information showing that previously-submitted diagnosis codes were not valid for risk adjustment purposes. For instance, certain codes may not be supported by medical record documentation. The duties imposed by the

risk adjustment regulations, including the duty to exercise due diligence and good faith in ensuring data accuracy, 42 C.F.R. § 422.504(1), and the duty to detect and correct non-compliance with CMS's program requirements, *id.* § 422.503(b)(4)(vi), require MAOs to delete unsupported diagnosis codes.

56. CMS also recognizes that, unless such codes are deleted or withdrawn, the inclusion of the inaccurate diagnosis codes will cause CMS to calculate—and make—higher risk adjustment payments to MAOs that it would not have made but for the submission of the inaccurate data. This, in turn, will result in the MAOs violating their regulatory and contractual obligations, as well as attestations, to ensure the accuracy of their risk adjustment data submissions. Accordingly, CMS includes a function in each of the risk adjustment data reporting systems —RAPS and EDPS—for MAOs to use to delete inaccurate diagnosis codes.

57. In addition to implementing the delete functions in RAPS and EDPS to enable MAOs to fulfill their regulatory obligation and attestations, CMS also provides instructions and training to MAOs on their responsibility to use this function to delete inaccurate diagnosis codes that they had submitted for risk adjustment purposes. For example, CMS instructs MAOs that if “upon conducting an internal review of submitted diagnosis codes,” they “determine[] that any ICD[] diagnosis codes that have been submitted do not meet risk adjustment submission requirements,” they are “responsible for deleting the submitted ICD[] diagnosis codes as soon as possible.” MMC Manual, Chap. 7 § 40 (June 2013).

58. Furthermore, it is important for the MAOs to timely report deletions of inaccurate diagnosis codes because deletions can directly affect the accuracy of CMS's final reconciliation calculation for each payment year. As noted above, as part of its reconciliation process, CMS may

make an additional payment to an MAO based on additional diagnosis codes reported before the final submission deadline or seek recoupment if the MAO deleted inaccurate diagnosis codes.

59. Finally, to ensure that MAOs fulfill their obligation to delete inaccurate diagnosis code submissions, CMS promulgated regulations and configured its risk adjustment data reporting systems to allow MAOs to submit deletions both before and after the final deadline for RAPS and EDPS data submissions. *See* 42 C.F.R. § 422.310(g)(2)(ii). In other words, while MAOs ordinarily are required to make final risk adjustment diagnosis data submissions by a specific deadline prior to receiving their final reconciliation payments for a given payment year, CMS requires MAOs to delete inaccurate diagnosis codes that had been previously submitted even *after* that deadline. This, in turn, enables CMS to recover risk adjustment payments associated with the deleted diagnoses as part of CMS's risk score rerun processes.

F. To Accurately Calculate Part C Risk Adjustment Payments CMS Imposed Regulatory and Contractual Obligations on Part C MAOs—including IBC—to Ensure the Accuracy of Their Diagnosis Codes

60. CMS promulgated regulations and annual agreements to define the obligations of MAOs under Medicare Part C. As set forth below, among the most important regulatory and contractual obligations of the MAOs are those pertaining to their responsibilities for ensuring the accuracy of the risk adjustment diagnosis data that they submit to CMS and for deleting inaccurate data that they previously submitted.

61. For example, throughout the relevant period, CMS required MAOs to implement effective compliance programs and defined this requirement as a prerequisite to MAOs obtaining and retaining payments under Part C. *See* 42 U.S.C. § 422.503(a). As CMS explained as early as June 2000, one purpose of requiring MAOs to implement compliance programs is to ensure that the information they submit to CMS is accurate and truthful. *See* 65 Fed. Reg. 40170-01 at 40264 (June 29, 2000).

62. At the outset, CMS’s Part C regulations require MAOs—including IBC—to “[a]dopt and implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with [] program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse.” 42 C.F.R. § 422.503(b)(4)(vi).

63. CMS’s Part C regulations specify that the compliance program that MAOs like IBC are required to implement “must, at a minimum, include [certain] core requirements,” which include, as relevant here:

- To establish and implement “an effective system for routine monitoring and identification of compliance risks,” which “should include internal monitoring and audits and, as appropriate, external audits,” to evaluate the MAO’s “compliance with CMS requirements and the overall effectiveness of the compliance program.”
- To establish and implement “procedures and a system for promptly responding to compliance issues as they are raised, investigating potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence, and ensuring ongoing compliance with CMS requirements.”

Id. § 422.503(b)(4)(vi)(E)-(F).

64. In the event these compliance programs uncover “evidence of misconduct related to payment,” CMS’ Part C regulations require IBC to “conduct a timely, reasonable inquiry into that conduct” and to undertake “appropriate corrective action,” including “repayment of overpayments.” 42 C.F.R. § 422.503(b)(4)(vi)(G). CMS’s Part C regulations also require IBC and other MAOs to “have procedures to voluntarily self-report potential fraud or misconduct related to [the Part C] program to CMS or its designee.” *Id.*

65. In addition to being subject to regulatory requirements, MAOs like IBC also agree in their Part C annual agreements to be responsible to CMS for ensuring the accuracy of their risk adjustment diagnosis data submissions.

66. By entering into these Agreements, IBC agreed to comply with CMS' requirements relating to the submission of diagnosis codes, including its obligation to affirmatively assess the accuracy of their diagnosis data submissions against the ICD coding guidelines and the medical record documentation standard. It similarly agreed to abide by CMS's requirement for MAO's to delete inaccurate diagnosis codes that they previously submitted. Relatedly, and in accordance with CMS regulations, *see* 42 C.F.R. § 422.510, the Part C annual agreement also specified that CMS could terminate IBC's participation in Medicare Part C if CMS determined that IBC had submitted false data or failed to provide CMS with valid risk adjustment data.

67. Furthermore, Medicare Part C regulations require MAOs like IBC to submit annual attestations to CMS for each of their Part C plans that, among other things, certify the accuracy of the risk adjustment diagnosis data they submitted for the relevant payment year. *See* 42 C.F.R. § 422.504(1). The Part C regulations further specify that the MAO's submission of their annual attestations is "a condition for receiving the monthly [capitated] payment" from CMS. *Id.*

68. As CMS repeatedly notified MAOs since June 2000, the purpose of the annual attestation requirement is to place the responsibility on MAOs like IBC to make "good faith efforts to certify the accuracy" of the risk adjustment data they submitted. *See* 65 Fed. Reg. 40,170, 50,268 (June 29, 2000); *see also* MMC Manual Chap. 7, § 111.7 (2004) ("CMS expects [MAOs] to design and implement effective systems to monitor the accuracy, completeness, and truthfulness of risk adjustment data and to exercise due diligence in reviewing the information provided to CMS").

69. During the relevant period, senior IBC executives signed and submitted annual attestations to CMS each year for the Part C plans operated by IBC and thus certified the risk adjustment information it submitted to CMS directly affects the calculation of CMS payments to IBC and that misrepresentation to CMS about the accuracy of such information may result in

Federal civil action and/or criminal prosecution. Having acknowledged that understanding, IBC further certified that all information submitted to CMS by IBC for risk adjustment payment purposes is accurate, complete, and truthful.

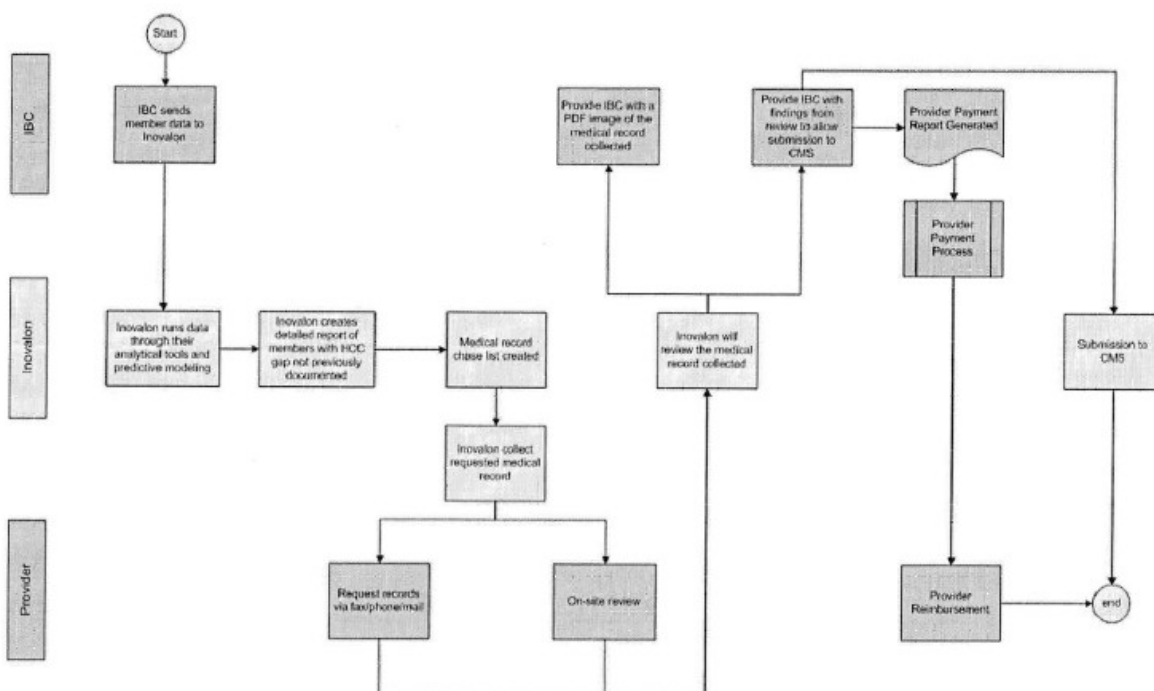
VI. FACTUAL ALLEGATIONS

70. During the Relevant Period, IBC implemented three separate retrospective code harvesting programs designed to identify and submit additional diagnosis codes and increase Medicare Advantage payments, but intentionally ignored—and failed to delete—inaccurate codes. By ignoring its duty to delete thousands of inaccurate diagnoses—*i.e.*, doing only “additions” and not “deletions”—IBC unlawfully obtained and retained tens of millions of dollars in payments under the risk adjustment payment system for Medicare Part C, in violation of the False Claims Act.

71. The three code harvesting programs were in-depth and expansive, and were specifically designed to identify and submit additional diagnosis codes to increase Medicare Advantage payments, but failed to locate and delete inaccurate diagnosis codes—all in order to increase Medicare revenue in violation of the applicable CMS rules and regulations. Ms. Crawford has firsthand knowledge regarding IBC’s code harvesting programs, that they were designed to intentionally focus solely on finding additional codes while willfully ignoring—and failing to identify and delete—inaccurate and unsubstantiated codes that IBC knew, based on known audit results, were likely to exist in its submissions to CMS, and that IBC received tens of millions of dollars in additional Medicare revenue as a result of these programs in violation of CMS rules and regulations, and which it otherwise would not have received but for these programs.

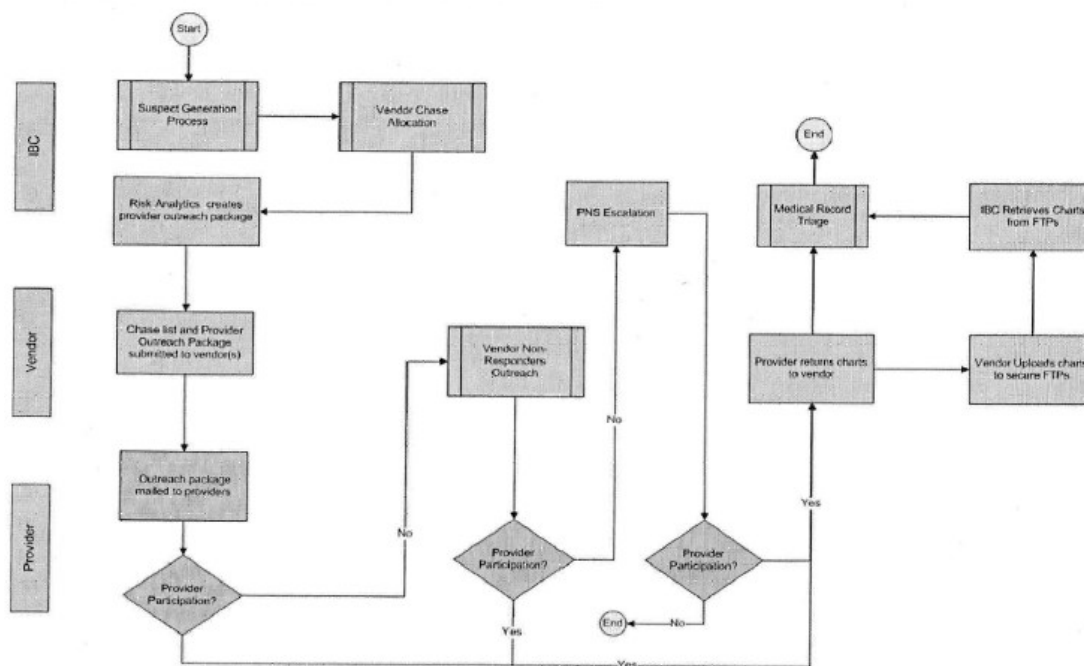
72. The first program—called the “CARA Program,” (*i.e.*, Capitated Risk Adjustment Process)—was performed by IBC’s third-party Vendor, Inovalon. The below is a chart illustrates the steps and processes for the CARA Program:

CARA – Process



73. The second program—called the “IBX Review”—was performed internally by IBC. The IBX Review entailed IBC personnel reviewing a full year’s worth of Medicare beneficiaries’ medical records for additional codes. The below chart illustrates the initial steps and processes for the IBX Review:

IBX Review – Process



74. After the steps outlined in the above chart, the IBX Review continued with additional steps including: (i) chart review process, where nursing personnel read the chart in the IBX Review application (which Ms. Crawford’s informatics team developed and maintained) and entered all of the additional applicable diagnosis codes; and (ii) the RAPS file generation process, where the diagnosis codes were extracted from the IBX Review application and created into a RAPS file that IBC submitted to CMS.

75. The third program—called the “EMR Data Exchange Program”—was performed internally by IBC using data extracted from third party data delivery systems. In particular, IBC paid a number of integrated delivery systems (“IDS(s)”) to send IBC data extracts from their providers’ EMR/EHR systems. The specific data fields varied by IDS, but typically contained discrete data fields with very specific, predictable types of data (such as specific ICD-9 or ICD-10 diagnosis codes from the Medicare beneficiaries’ list of active problem codes, rather than data from open-ended text fields like the doctors’ prognosis/visit notes about the beneficiaries). IBC

then compiled all the additional diagnosis codes from the discrete data fields and converted them directly into a RAPS file that IBC then submitted to CMS. At no point during the EMR Review, however, did IBC confirm the accuracy of the additional diagnosis codes or whether the beneficiary still had or was being monitored, evaluated, assessed or treated for that particular diagnosis—and IBC made no effort to locate and delete inaccurate diagnosis codes as part of the EMR Review process. In fact, as a result of the EMR Review, IBC routinely submitted to CMS diagnosis codes for conditions that were inaccurate (such as diagnosis codes for unstable angina (ICD-10-120), accurate myocardial infarction (ICD-10-167) and acute respiratory failure (ICD-10-J96)) not diagnosed in an acute setting.

76. The sole purpose of these three code harvesting programs was to increase revenue by submitting additional diagnosis codes to CMS, while intentionally ignoring—and failing to delete—inaccurate codes that could not be substantiated by the medical records.

77. IBC's profits and revenues from its code harvesting programs has been significant. In 2015, for example, the CARA Program reviewed more than 90,839 charts for Medicare beneficiaries, and the IBC's Review reviewed more than 54,453 charts. That same year, while IBC spent \$6 million on its CARA Program to review Medicare beneficiaries' charts, IBC's total 2015 Medicare Revenue generated by the CARA Program alone was **\$23.1 million**, equaling a 2015 **Medicare return on investment of 3.85 to 1**. The below chart illustrates this significant profit:

Program	2015 Medicare Spend	2015 Commercial HIX Spend	2015 Total Program Spend	2015 Medicare Revenue	2015 Medicare ROI
Retrospective					
CARA	\$6.0 M	\$8.2 M	\$14.2 M	\$23.1 M ?	3.85 to 1

78. Beginning in 2016 and, upon information and belief, continuing to the present, the IBX Review replaced the CARA Program and brought the third party work in-house to reduce IBC external costs, thereby further increasing IBC's Medicare profits and return on investment.

79. IBC knew that the results of its code harvesting programs could indicate whether the diagnosis codes IBC previously submitted to CMS were accurate. For instance, IBC regularly conducted sample audits of its CMS submissions; and when inaccurate submissions were identified in the sample audit set, they were deleted. This practice was confirmed by Ms. Crawford's colleague at IBC: an audit nurse in IBC's Government Markets department. Ms. Crawford generally recalls that the internal audit results consistently found IBC's CMS submissions to have inaccuracy rates between 10–15%. Despite the foregoing, IBC implemented its code harvesting program to find additional diagnosis codes to submit to CMS, while knowingly and intentionally failing to delete unsubstantiated codes that IBC knew, based on known audit results, were likely to exist and submitted to the Government.

80. While IBC could have readily written a computer algorithm to find inaccurately reported diagnosis codes by comparing previously-submitted codes against program results, IBC made no effort to do so during the Relevant Period. By taking the simple step of comparing its previously-submitted codes against its program results, IBC would have been able to identify the instances where an inaccurate diagnosis code was submitted to CMS.

81. However, IBC viewed its code harvesting programs solely as a means to identify and generate new diagnosis codes to allow it to obtain higher Medicare payments. Indeed, finding and deleting inaccurate diagnosis codes would have lead CMS to calculate lower risk adjustment payments to IBC, resulting in reduced revenue from Medicare.

82. Ultimately, the extraordinary profits that IBC obtained through its code harvesting programs came at the expense of the Government. By knowingly disregarding its regulatory and contractual obligations to correct—and delete—inaccuracies in its diagnosis data submissions, IBC improperly obtained or retained millions of dollars from the Government in violation of the False Claims Act. Upon information and belief, Relator estimates that IBC’s one-sided code harvesting programs (*i.e.*, focusing solely on finding additional codes to submit to CMS without also identifying and deleting inaccurate codes) ***generated \$20 million or more per year in additional revenue for IBC.***

83. Ms. Crawford was employed at IBC from September 2013 to November 2016, where she worked in the Informatics department as an analyst, manager, and eventually Director of IBC’s Risk Adjustment Business Processes. In those roles, she helped develop and manage IBC’s programs, and was responsible for overseeing the development of software and processes to identify and retrieve diagnosis codes for submission to the Government. She has firsthand knowledge that IBC’s code harvesting programs were designed to intentionally focus solely on finding additional codes to submit, that IBC generated significant revenue as a result of these programs, and that IBC was aware of inaccuracies in its CMS submissions, yet willfully ignored and failed to identify and delete inaccurate codes.

84. In sum, IBC has defrauded the Government by submitting inaccurate risk adjustment diagnosis data by conducting retrospective code harvesting programs to find additional codes to submit to the Government, but failing to identify and delete inaccurate codes. The fraud was material to payment by the Government. Had the Government known about the inaccurate diagnosis codes, it would not have paid IBC higher payments under the risk adjustment payment system for Medicare Part C.

COUNT ONE
VIOLATION OF THE FALSE CLAIMS ACT
31 U.S.C. § 3729(a)(1)(A)

85. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

86. Relator seeks relief against IBC under section 3729(a)(1)(a) of the FCA, 31 U.S.C. § 3729(a)(1)(A), because IBC knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval to CMS during the Relevant Period.

87. Specifically, on account of its choice to operate its programs in deliberate ignorance or reckless disregard of its regulatory and contractual obligation to delete inaccurate diagnosis codes, IBC knowingly submitted false Part C annual attestations to CMS in connection with seeking final reconciliation payments from Medicare.

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

89. If CMS had known that IBC's attestation was false because, at the time of the attestation, IBC knew that specific diagnosis codes it had submitted for payment and never deleted were inaccurate, CMS would have taken appropriate actions to ensure that IBC did not receive or retain risk-adjustment payments to which it was not entitled, including by recouping payments through administrative processes, adjusting the reconciliation payments, or obtaining repayments in enforcement actions.

COUNT TWO
VIOLATION OF THE FALSE CLAIMS ACT
31 U.S.C. § 3729(a)(1)(B)

90. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

91. Relator seeks relief against IBC under Section 3729(a)(1)(B) of the FCA, 31 U.S.C. § 3729(a)(1)(B), because IBC knowingly made, used, or caused to be made or used, a false record or statement material to a false or fraudulent claim during the Relevant Period.

92. Specifically, on account of its choice to operate its programs in deliberate ignorance or reckless disregard of its regulatory and contractual obligation to delete inaccurate diagnosis codes, IBC knowingly made, used, or caused to be made or used, false Part C annual attestations in relation to seeking final reconciliation payments from Medicare.

93. By reason of these false records or statements, the Government has been damaged in a substantial amount to be determined at trial and is entitled to recover treble damages plus a civil monetary penalty for each false record or statement.

94. If CMS had known that IBC's attestation was false because, at the time of the attestation, IBC knew that specific diagnosis codes it had submitted for payment and never deleted were inaccurate, CMS would have taken appropriate actions to ensure that IBC did not receive or retain risk-adjustment payments to which it was not entitled, including by recouping payments through administrative processes, adjusting the reconciliation payments, or obtaining repayments in enforcement actions.

COUNT THREE
VIOLATION OF THE FALSE CLAIMS ACT—REVERSE FALSE CLAIM
31 U.S.C. § 3729(a)(1)(G)

95. Relator incorporates by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

96. Relator seeks relief against IBC under Section 3729(a)(1)(G) of the FCA, 31 U.S.C. § 3729(a)(1)(G), both because IBC knowingly made or used a false record or statement material to an obligation to repay the Government and because IBC knowingly concealed or knowingly and improperly avoided an obligation to repay the Government during the Relevant Period.

97. Specifically, on account of its choice to operate its programs in deliberate ignorance or reckless disregard of its regulatory and contractual obligation to delete inaccurate diagnosis codes, IBC knowingly made, used, or caused to be made or used, false Part C annual attestations that enabled it to evade its obligation to refund CMS under the Medicare Part C's final reconciliation process.

98. Further, by deliberately or recklessly disregarding its regulatory and contractual obligation to delete inaccurate diagnosis codes, IBC knowingly concealed its obligation to refund CMS.

99. By reason of these false records or statements, as well as IBC's knowing concealment and avoidance, the Government has been damaged in a substantial amount to be determined at trial and is entitled to recover treble damages plus a civil monetary penalty for each false record or statement.

PRAYER FOR RELIEF

WHEREFORE, the Government and Relator demand that judgment be entered against Defendant and in favor of the Relator and Government as follows:

On Count One through Count Three under the federal False Claims Act for the amount of the United States' damages, multiplied by three as required by law, and such civil penalties as are permitted or required by law; the maximum share amount allowed pursuant to 31 U.S.C. § 3730(d); all costs and expenses of this action, including attorney fees, expenses and costs as permitted by

31 U.S.C. § 3730(d); and all such other relief as may be just and proper.

REQUEST FOR TRIAL BY JURY

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator hereby demands a trial by jury.

Dated: November 18, 2020

Respectfully submitted,

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** Pro hac vice applications forthcoming*