UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

United States *ex rel.* Clarissa Zafirov,

Plaintiff/Relator,

v. CASE NO. 8:19-cv-01236-SDM-SPF

Florida Medical Associates, LLC d/b/a VIPcare; Physician Partners, LLC; Physician Partners Specialty Services, LLC; Sun Labs USA, Inc.; Anion Technologies, LLC; Anthem, Inc.; Freedom Health, Inc.; Optimum Healthcare, Inc.; and Siddhartha Pagidipati,

Defendants.
______________________________/

FLORIDA MEDICAL ASSOCIATES, LLC, PHYSICIAN PARTNERS, LLC, PHYSICIAN PARTNERS SPECIALTY SERVICES, LLC, SUN LABS USA, INC., AND ANION TECHNOLOGIES, LLC'S MOTION TO DISMISS COMPLAINT FOR FAILURE TO STATE A CLAIM

The purported whistleblower in this case, Clarissa Zafirov, is a relatively junior physician who performed primary care services at Florida Medical Associates, LLC ("FMA") for only *seven* months before filing her *qui tam* suit. She was an employee of FMA, where she began working shortly after she completed her residency program. She was not just new to the practice of medicine; she also had no prior experience with Medicare Advantage, a specialized federal healthcare program that is at the heart of this case. Zafirov's lack of understanding of Medicare Advantage, and her lack of knowledge about billing practices, is evident throughout her complaint.

The fundamental errors in Zafirov's complaint stem not only from her inexperience with Medicare Advantage, but also from her lack of first-hand knowledge about any alleged false claims. Her tenure as an employee was narrowly circumscribed: she saw a limited number of

patients at one of FMA's smaller offices in Venice, Florida. Neither she nor anyone in her office ever submitted a claim to a Medicare Advantage Organization, much less to the government. Neither she nor anyone in her office ever submitted risk adjustment score computations for patients. Neither she nor anyone in her office in Venice ever reviewed the payments that the government made to Medicare Advantage Organizations.[1]

Against this backdrop, Defendants FMA, Physician Partners, LLC ("Physician Partners"), Physician Partners Specialty Services, LLC ("Physician Partners Specialty Services"), Sun Labs USA, Inc. ("Sun Labs"), and Anion Technologies, LLC ("Anion") (collectively, the "Provider Defendants") move to dismiss Zafirov's complaint.

ARGUMENT

Zafirov's complaint is legally deficient for at least six reasons: (1) it fails to plead fraud with sufficient particularity; (2) Zafirov has not and cannot show that any false claim was material to a government payment decision; (3) Zafirov's allegations are implausible; (4) the complaint is barred by the first-to-file doctrine; (5) Zafirov's allegations were publicly disclosed years ago; and (6) the complaint is foreclosed by the government action bar. Given these defects, and Zafirov's lack of knowledge about any billing practices at any Defendant, leave to amend would be futile.

[1] The Medicare Advantage Organizations named here are Freedom Health, Inc. ("Freedom") and Optimum Healthcare, Inc. ("Optimum") (collectively, the "Medicare Advantage Defendants").

I. Zafirov has not pleaded fraud with particularity.

A. The Complaint impermissibly lumps all defendants together without specifying who did what.

As a threshold defect, the Complaint fails because it alleges every defendant did everything wrong. This type of conclusory pleading is impermissible. Courts routinely dismiss complaints that "assert[] multiple claims against multiple defendants without specifying which of the defendants are responsible for which acts or omissions." *Weiland v. Palm Beach Cty. Sheriff's Office*, 792 F.3d 1313, 1323 (11th Cir. 2015). The Eleventh Circuit "ha[s] condemned repeatedly" this style of complaint. *Magluta v. Samples*, 256 F.3d 1282, 1284 (11th Cir. 2001).

The Complaint names nine different defendants but fails to specify who did what, much less when, where, and how. Instead, Zafirov lumps together five separate corporate entities—FMA, Physician Partners, Physician Partners Specialty Services, and Sun Labs—as the "PO Defendants" and then makes collective assertions of fraud against them. She makes no allegations whatsoever about Physician Partners Specialty Services, but simply identifies it as a party. Compl. ¶ 7.c. Her only specific allegation about Physician Partners is that it gave doctors a manual on how to use the 5 Star Checklists. Compl. ¶¶ 55, 62. And her only specific allegation about Sun Labs is that it issued her paycheck. Compl. ¶¶ 6, 7.d. Because Zafirov does not allege the role of each defendant in the alleged scheme, she cannot plausibly allege that the defendants acted *knowingly* in the scheme. *See Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2002 (2016) (noting that the False Claims Act's scienter requirement is "rigorous").

B. Zafirov has not pleaded fraud with the requisite particularity

Putting aside the plural pleading, the complaint fails to plead even one false *claim* with the requisite particularity. "The submission of a false claim is . . . the *sine qua non* of a False Claims Act violation." *United States ex rel. Clausen v. Lab. Corp. of Am.*, 290 F.3d 1301, 1302 (11th Cir.

2002). Allegations of purportedly "improper practices alone are insufficient to state a claim under the False Claims Act absent allegations that a specific fraudulent claim was in fact submitted to the government." *Corsello v. Lincare, Inc.*, 428 F.3d 1008, 1014 (11th Cir. 2005).

To plead with particularity her direct false claims count under 31 U.S.C. § 3729(a)(1)(A), Zafirov must "allege the 'who,' 'what,' 'when,' and 'how' of fraudulent submission." *Hopper v. Solvay Pharms., Inc.*, 588 F.3d 1318, 1326–27 (11th Cir. 2009). To plead with particularity her false records count under 31 U.S.C. § 3729(a)(1)(B), Zafirov "must identify the particular document and statement alleged to be false, who made or used it, when the statement was made, how the statement was false, and what the defendants obtained as a result." *United States ex rel. Matheny v. Medco Health Solutions, Inc.*, 671 F.3d 1217, 1225 (11th Cir. 2012). She does neither.

1. Zafirov has failed to plead any specific false claims.

Zafirov has not alleged a *single* false claim in her Complaint. Nor has she identified one increased payment that resulted from an allegedly false diagnosis. The Complaint fails to provide any information essential to allege a false claim: which of the Provider Defendants—much less, which *individual* at a specific Provider Defendant—entered a false diagnosis code, when that code was entered, which of the Medicare Advantage Defendants submitted the code to CMS, or when it was submitted. She does not plead this information because she does not know it and could not have known it given her limited scope of employment as a physician with no access to or knowledge of the Defendants' billing practices. And, as such, any amendment would be futile.

Zafirov instead assumes that false claims *must* have been submitted because FMA employed "5 Star Checklists" and paid bonuses to some physicians. Yet, untethered allegations of misconduct that bear no connection to a specific false claim have never been sufficient to pass muster under Rule 9(b). Nor should they be sufficient now. Zafirov cannot rely on allegedly

improper practices to support "the inference that fraudulent claims were submitted"; rather, a "submission must be pleaded with particularity and not inferred from the circumstances." *Corsello*, 428 F.3d at 1013. Without showing that the 5 Star Checklists or doctor bonuses "ever converged to produce an actual false claim," Zafirov cannot state any False Claims Act violation. *Carrel v. AIDS Healthcare Foundation, Inc.*, 898 F.3d 1267, 1277 (11th Cir. 2018).

Even when Zafirov cites examples of patients whose diagnoses were allegedly falsified, she fails to allege "details related to the submission of a claim to Medicare, such as the date the claim was submitted or the amount of the payment requested." *See United States v. Fazzi Assocs., Inc.*, No. 1:15-cv-511, 2019 WL 6117299, at *7 (S.D. Ohio Nov. 18, 2019). She does not plead this because she cannot. She was never involved with billing or submission of any claim by the Medicare Advantage Defendants. That Zafirov must rely on allegations made "on information and belief" to support her claim underscores her lack of knowledge. *See* Compl. ¶¶ 72, 73. Allegations based "on information and belief" lack the "indicia of reliability" to allege a false claim. *See Corsello*, 428 F.3d at 1013–14.

In short, "[t]he complaint does little more than hazard a guess that [the Medicare Advantage Defendants] submitted false claims for Medica[re] reimbursement." *Hopper*, 588 F.3d at 1326. Because Zafirov has no "personal knowledge of the payment terms or billing practices," she cannot state a False Claims Act violation. *United States ex rel. Seal 1 v. Lockheed Martin Corp.*, 429 F. App'x 818, 820 (11th Cir. 2011).

2. Zafirov does not plead any false attestations by any of the Provider Defendants.

Zafirov does no better with her false records claim. This claim appears to be based on allegedly false attestations submitted by the Provider Defendants or the Medicare Advantage Defendants to CMS. *See* Compl. ¶ 42. Under CMS regulations, Medicare Advantage organizations must attest that their risk adjustment data is complete and accurate to the best of their knowledge, information, and belief. *See* 42 C.F.R. § 422.504(*l*). However, Zafirov does not identify any CMS regulation requiring *providers* to make such attestations or allege that any such attestations were made by any of the Provider Defendants. Zafirov's failure to identify any attestations, let alone any *knowingly false* attestations, requires dismissal of her false records claim. *See United States v. Scan Health Plan*, No. CV 09-5013-JFW (JEMx), 2017 WL 4564722, at *6 (C.D. Cal. Oct. 5, 2017). Again, Zafirov fails to plead these facts because she does not know them. No such facts exist.

II. Zafirov has not shown that the allegedly false statements or regulatory violations were "material" under *Escobar*.

Zafirov also fails to plead that any allegedly false statements were material. She does not plead materiality because she cannot. As this Court knows, the False Claims Act's materiality requirement is "rigorous" and "demanding." *Escobar*, 136 S. Ct. at 2002, 2003. The Supreme Court has held that the materiality requirement should be "strict[ly] enforce[d]" at the motion to dismiss stage. *Id.* at 2002, 2004 n.6. Zafirov bears the burden of "pleading facts to support allegations of materiality." *Id.* at 2004 n.6. She has failed to do so.

The complaint says almost nothing about materiality. Apart from quoting the statutory definition (Compl. ¶ 25), Zafirov's two counts against "All Defendants" allege, in conclusory fashion, that CMS "would have refused to make risk-adjusted payments to the MA Defendants" had it "been aware of" the "false coding." *Id.* ¶¶ 99, 103. The Supreme Court in *Escobar*

specifically held such allegations are insufficient. "A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment. *Nor is it sufficient for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant's noncompliance*." 136 S. Ct. at 2003 (emphasis added).

Nothing else in the complaint suffices to satisfy the materiality standard. Zafirov does not identify any express certification either signed by the Provider Defendants or presented to CMS. Therefore, her complaint against them must rest on an "implied certification" theory. *See Escobar*, 136 S. Ct. at 2001. To establish False Claims Act liability on this theory, two conditions must be satisfied: (1) "the claim does not merely request payment, but also makes representations about the goods or services provided" *and* (2) "the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths." *Id.* Zafirov cannot satisfy either *Escobar* condition.

First, Zafirov has no knowledge of and does not plead a single false diagnosis code that the Provider Defendants presented to CMS. The complaint contains allegations about only five patients with allegedly false diagnosis codes that were (in passive tense) "billed" or "submitted." Compl. ¶¶ 70, 72, 73, 74, 75.[2] These sparse allegations are insufficient to satisfy the first *Escobar* condition. Primarily, the allegation fails because a diagnosis code is not a "request [for] payment." Zafirov concedes that "[n]ot all diagnosis codes result in an adjustment in risk score and thus not all diagnosis codes affect payment." Compl. ¶ 33. Because she was not involved in any billing or claim submission while employed at FMA, Zafirov does not tie any of the five allegedly false

[2] Zafirov's allegations about inadequate patient care (Compl. ¶¶ 89–90) and physician bonuses (*id.* ¶¶ 80–88) have nothing to do with claims for payment from the government and thus cannot lead to False Claims Act liability.

diagnosis codes to a specific Provider Defendant or explain how any false code made its way from a Provider Defendant, through a Medicare Advantage insurer, to CMS. Even assuming that the five diagnosis codes were "false," the complaint is devoid of any allegation that a misdiagnosis resulted in a higher risk score for a patient or a higher capitated payment in the following year. Nitpicking "only a subset of a subset of the data" reported to CMS under a program as complex as risk scoring cannot satisfy the materiality requirement. *United States ex rel. Janssen v. Lawrence Mem'l Hosp.*, 949 F.3d 533, 543–44 (10th Cir. 2020).

Second, Zafirov does not identify any "material statutory, regulatory, or contractual requirement" that the Provider Defendants violated. *Escobar*, 136 S. Ct. at 2001. She contends that the "MA Defendants" breached their overpayment obligations established by the 2013 Medicare Managed Care Manual. Compl. ¶ 92. This Manual, though, is not a statute, not a regulation, and not a contract. It is non-binding guidance provided to the Medicare Advantage Defendants, not the Provider Defendants. With no allegation that any Provider Defendant violated any statute, regulation, or contractual requirement that was material to CMS's payment decisions, Zafirov's claims fail for lack of materiality. *See United States ex rel. Rasmussen v. Essence Grp. Holdings Corp.*, No. 17-3273-CV-S-BP, 2020 WL 4381771, at *5–7 (W.D. Mo. Apr. 29, 2020).

Zafirov is unsuccessful at making a False Claims Act case from general criticisms of the 5 Star Checklists. There is nothing wrong or illegal in using chart review to fully assess the health risks that any given patient poses to an insurance pool. *See Rasmussen*, 2020 WL 4381771, at *4–*5 (citing *Untied States ex rel. Gray v. UnitedHealthcare Ins. Co.*, No. 15-cv-7137, 2018 WL 2933674, at *7 (N.D. Ill. Jun. 12, 2018)). CMS has repeatedly investigated and approved chart review as a means of collecting diagnosis codes, notwithstanding its concerns that such review could increase payments. *See* HHS OIG, *Billions in Estimated Medicare Advantage Payments*

from Chart Reviews Raise Concerns 4 (Dec. 2019), https://oig.hhs.gov/oei/reports/oei-03-17-00470.asp (stating that MAOs "may employ third-party vendors to examine beneficiaries' medical records by using staff with clinical or coding experience or by using artificial intelligence software. MAOs may report diagnoses identified by these reviews to the encounter data as chart review records . . . ."); CMS, *Announcement of Calendar Year (CY) 2016 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter* 34 (Apr. 6, 2015), https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2016.pdf (noting that encounter data system to which CMS is transitioning "accepts diagnoses obtained through chart review").

Zafirov also cannot establish materiality because CMS knows about diagnosis coding errors yet continues to pay, both generally and in this case. Generally, in the Medicare Advantage context, the government is aware that there is a margin of error built into claims data submitted to it and the government expressly accounts for this error. *See UnitedHealthcare Ins. Co. v. Azar*, 330 F. Supp. 3d 173, 180 (D.D.C. 2018). More specifically to this case, CMS—through review of annual Independent Review Organization reports—audits the Medicare Advantage insurers here as part of the *Sewell* settlement and Corporate Integrity Agreement. *See* **Exhibit A**, at App'x C. This includes their diagnosis codes. *Id.* CMS continues to pay capitated payments every year, despite the allegations in *Sewell* and here. The government's decision to continue paying capitated payments to the Medicare Advantage insurers here belies any allegation that erroneous or false diagnosis codes are material.[3] "[I]f the Government pays a particular claim in full despite its actual

---

[3] Further, even if there was a concern with certain diagnoses codes (which there is not) CMS' own guidance provides a six-year lookback for the remittance of any overpayments. *See* CMS, *Guidance for Reporting and Returning Medicare Advantage Organization and/or Sponsor Identified Overpayments to the Center for Medicare & Medicaid Services* 3 (Feb. 18, 2015),

knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material." *Escobar*, 136 S. Ct. at 2003.

Finally, the government's decision not to intervene shows that any allegedly incorrect diagnosis coding was not material. *See* Doc. 40 (government's notice of election to decline intervention); *Polansky v. Executive Health Res.*, 422 F. Supp. 3d 916, 938 (E.D. Pa. 2019) ("Post-*Escobar*, numerous federal courts have found insufficient FCA materiality where the government investigated a relator's allegations but chose not to intervene or otherwise address the defendant's allegedly improper behavior."). The government has investigated Zafirov's allegations and declined to take action, either in this *qui tam* action or under the Corporate Integrity Agreement from *Sewell*. Zafirov therefore cannot plausibly allege that any of the Defendants' actions affected the government's payment decision.

III. Zafirov's claims are implausible.

The complaint also fails because its allegations about both false claims and false records are implausible.

A. Zafirov cannot plausibly allege the Provider Defendants caused the presentment of any false claims or caused the government to pay any false claims.

Zafirov's theory of "fraud" is that the Provider Defendants' business practices caused physicians to improperly diagnose patients. Her primary focus is on the 5 Star Checklists. The 5 Star Checklists gather available information about a patient's potential current medical conditions in a single place for physicians to review as they evaluate a patient. This information is gathered by algorithms that aggregate historical data in a patient's medical charts to identify possible disease conditions for physicians to consider and, if appropriate, evaluate using their independent clinical

---

https://csscoperations.com/internet/cssc3.nsf/files/Overpayment%20Memo02182015.pdf/$FIle/Overpayment%20Memo02182015.pdf.

judgment. Zafirov's theory is that the 5 Star Checklists cause the Provider Defendants' physicians to write incorrect diagnoses. This theory is implausible as (1) physician judgment, not a checklist, reigns supreme in medical decision-making and (2) even if there was "pressure" to apply incorrect diagnosis codes—which there was not—the chain of causation is too attenuated to support liability.

1. *Physician judgment is the starting—and ending—point for medical diagnoses.*

Zafirov's theory is not plausible. A physician uses her medical judgment, not a checklist, to diagnose patients. Zafirov admits that 5 Star Checklists are not diagnoses; they are simply a list of potential medical conditions based on information in a patient's medical files. *See* Compl. ¶¶ 55–56. She asserts that patients sometimes do not suffer from certain conditions included on the Checklist. But her allegations highlight the fact that a physician must ultimately bring her medical judgment to bear to form a diagnosis. This is exactly what Zafirov allegedly did. *See* Compl. ¶¶ 67, 70, 71, 72. By way of analogy, Westlaw may suggest authorities based on a researcher's search terms. But a lawyer must read and analyze those authorities to decide whether to cite them in her brief. Like Westlaw's "smart" search results, 5 Star Checklists are created by filtering large amounts of data to identify conditions that a physician might consider in forming her professional opinion. Ultimately, however, the physician must decide on the appropriate diagnosis, as the lawyer must decide on which cases to cite in her brief.

It is telling that Zafirov has not alleged that the 5 Star Checklists or any of the Defendants' other allegedly improper practices interfered with any physician's medical judgment. To the contrary, her allegations reveal the opposite. Zafirov notes that her employment agreement gives her exclusive control over her medical judgment and nothing in the agreement interferes with her professional autonomy. Compl. ¶ 81. It is also clear from the Complaint that Zafirov was exercising her professional judgment by rejecting 5 Star Checklist's data points.

Zafirov is equally unsuccessful in her allegation that the Provider Defendants caused physicians to schedule medically unnecessary visits with patients for the sole purpose of obtaining diagnosis codes. Compl. ¶ 49.a. Unlike fee-for-service Medicare, CMS does not pay the Provider Defendants for each visit. Additional visits cost providers and insurers more money. If the Defendants' only goal were to capture codes, they would not need to schedule regular visits—they could capture all codes in a single visit. What is more, Zafirov cannot square her claims about unnecessary visits with her later suggestion that the defendants withheld necessary care from patients.[4] Zafirov's theories are therefore not plausible. *See Rasmussen*, 2020 WL 4381771, at *4 (holding that alleged "medically unnecessary" office visits "cannot support a claim under the FCA" because CMS is not billed for them).

Physicians exercising medical judgment make diagnoses. Zafirov does not allege that anyone forced her (or anyone else) to misdiagnose a patient. Nor does she allege that the business practices she faults caused a physician to change a diagnosis code. Thus, these allegations must fail for lack of plausibility.

2. Zafirov's Theory Establishes a Far Too Attenuated Theory of Causation

Zafirov's theory of presentment of false claims is implausible for a second reason: it simply stretches the theory of causation too far. As noted above, the ultimate diagnosis of any patient turns on the physician's clinical judgment. No claim can be submitted unless a physician herself signs off on the diagnosis.

Notwithstanding this, Zafirov seeks to shift liability to the Provider Defendants, who do not have contracts with CMS and do not present any diagnosis codes to CMS. Physician Partners

[4] Zafirov's allegations concerning the quality of patient care have no bearing on her claims that the defendants submitted false diagnosis codes to the government. The Court should disregard those allegations.

and FMA submit diagnosis codes to the Medicare Advantage Defendants, but these diagnosis codes are not requests for payment. As Zafirov acknowledges, "[n]ot all diagnosis codes result in an adjustment in risk score and thus not all diagnosis codes affect payment." Compl. ¶ 33. Raw diagnosis codes do not entitle Physician Partners, the only Provider Defendant in privity with Freedom or Optimum, to receive payment, either from a Medicare Advantage Defendant or the government. Moreover, raw diagnosis codes are meaningless for risk adjustment purposes.

Before a diagnosis code can even *possibly* lead to increased payment, Medicare Advantage insurers must subject these codes to multiple levels of processing and review. Medicare Advantage insurers must verify that the code came from one of three acceptable data sources: a hospital inpatient stay, an outpatient facility, or a physician. CMS, Pub. No. 100-16, *Medicare Managed Care Manual*, ch. 7, § 120 (2014), https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c07.pdf. They must then format the codes along with four other data points (claim number, service from date, service through date, and provider type) into "diagnosis clusters" for submission to the Risk Adjustment Processing System (RAPS).[5]

[5] CMS also uses the Encounter Data Processing System (EDPS), to translate diagnosis codes into risk adjustment data. *See* CMS, *Encounter Data Submission and Processing Guide* 11 (2018), https://www.csscoperations.com/internet/cssc4.nsf/files/ED_Submission_Processing_Guide.pdf/$FIle/ED_Submission_Processing_Guide.pdf. The EDPS relies on "encounter data," which is "data representing each item and service provided to a Medicare Advantage enrollee," to calculate risk adjustment scores. *Id.* at ch. 1.1. Like the RAPS, the EDPS also contains multiple levels of review and processing as it translates diagnosis data into risk adjustment data. *See id.* at Figure 1.1; ch. 1.3. Although CMS seeks to rely more heavily on the EDPS to calculate risk scores going forward, the RAPS was the primary determinant of Medicare Advantage patients' risk scores during the relevant timeframe. *See* CMS, *2021 Medicare Advantage and Part D Advance Notice Part II Fact Sheet* (Feb. 5, 2020), https://www.cms.gov/newsroom/fact-sheets/2021-medicare-advantage-and-part-d-advance-notice-part-ii-fact-sheet (explaining that the RAPS accounted for 75–90 percent of patients' risk scores between 2015 and 2019). Thus, this brief's focus is on the RAPS.

Id. Medicare Advantage insurers then "submit the five data elements in the RAPS format . . . to the Front End Risk Adjustment System (FERAS) for initial edit checks." *Id.*

FERAS and RAPS are the first layer of Medicare Advantage insurers' array of tools to verify their risk adjustment data. After Medicare Advantage insurers submit diagnosis clusters, FERAS and RAPS generate various reports identifying errors and showing the disposition of entered data "so plans can verify their data and project their payment." *Id.* Medicare Advantage insurers review these reports to identify and correct errors, including duplicate diagnosis clusters. *See id*. § 120.2.5. After editing, "[f]inalized diagnosis clusters are stored in the RAPS database and used for the calculation of risk scores." *Id*. § 120. CMS also generates several reports, including Monthly Membership Reports and Model Output Reports, for insurers to verify their data. *See id.* § 120.3.

This multi-layered processing and review system breaks any causal link between the Provider Defendants' raw diagnosis codes and the finalized risk adjustment data the Medicare Advantage Defendants submit for payment. This alone requires dismissal of the direct false claims count, because the Provider Defendants could not have "[themselves] submitt[ed] or directly caus[ed] the submission of a false claim." *Hopper*, 588 F.3d at 1329. *See also United States ex rel. Bane v. Breathe Easy Pulmonary Servs., Inc.*, 597 F. Supp. 2d 1280, 1292 (M.D. Fla. 2009) (stating that there must be "a strong and direct causal link between the defendant's actions and the submission of a false claim" and holding that link was missing where downstream entity "had no control over" Medicare entity's claims procedures, "gave no suggestion or instruction . . . regarding its Medicare submissions, and in no way participated in . . . submission of bills to Medicare").

Moreover, an incorrect diagnosis code itself does not lead to increased payment. Diagnoses are classified according to severity "so that a person is coded only for the most severe manifestation among related diseases." CMS, *Report to Congress: Risk Adjustment in Medicare Advantage* 17 (Dec. 2018), https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/RTC-Dec2018.pdf. The CMS-HCC also excludes diagnoses that are vague or nonspecific (like symptoms), discretionary, medically insignificant, and transitory or definitively treated. *Id.* at 19. The model also considers demographic information, like sex and age. *Id.* at 20. The ultimate capitated payment is a complex multi-dimensional calculus that does not turn on any single input. CMS takes into account geography, the bid submitted by the insurer, the number of patients, and other factors in deciding the capitation rate to an insurer. *See Azar*, 330 F. Supp. 3d at 178; 42 C.F.R. § 422.308. Due to this complex calculus, any causal link between an incorrect diagnosis and an increased payment is too attenuated to support Zafirov's theory of false claims.

B. Zafirov has not plausibly alleged any objectively false claims or records.

Zafirov has not shown that any of the Provider Defendants' diagnosis codes were objectively false. As the Eleventh Circuit recently held, for a claim to be "false" under the False Claims Act, a relator "must show an objective falsity." *United States v. AseraCare, Inc.*, 938 F.3d 1278, 1298 (11th Cir. 2019). In the context of medical judgments like the diagnoses at issue here, "a reasonable difference of opinion among physicians reviewing medical documentation *ex post* is not sufficient on its own to suggest that those judgments—or any claims based on them—are false under the FCA." *Id.* at 1297. Zafirov's disagreements with the potential diagnoses identified by the 5 Star Checklists and ultimately diagnosed by other physicians do not plausibly allege any objectively false claims or records. Zafirov's second-guessing other physicians cannot be the basis of a False Claims Act violation.

Zafirov's references to allegedly improper corporate practices likewise do not state any objectively false claims. Zafirov must show that "the clinical judgment on which the claim is based contains a flaw that can be demonstrated through verifiable facts." *Id.* She cannot do this by merely second-guessing other physicians and questioning the Provider Defendants' business practices.

IV. Because there is analogous *qui tam* action pending in this District, the Court should dismiss this case under the FCA's first-to-file rule.

Under the False Claims Act's "first-to-file" bar, "[w]hen a person brings an action under [the FCA], no person other than the Government may intervene or bring a related action based on the facts underlying the pending action." 31 U.S.C. § 3730(b)(5). In other words, the first-to-file bar *only* "permits courts to exercise jurisdiction over the *first* privately-commenced *qui tam* claim filed based on a particular set of facts." *Makro Capital of Am. v. UBS AG*, 543 F.3d 1254, 1257 (11th Cir. 2008) (emphasis added). If another, similar *qui tam* action is already pending, no further actions lie. Courts assess similarity "by comparing the complaints side-by-side, and asking whether the later complaint 'alleges a fraudulent scheme the government already would be equipped to investigate based on [the first] [c]omplaint.'" *See United States ex rel. Heath v. AT&T, Inc.,* 791 F.3d 112, 121 (D.C. Cir. 2015) (quoting *United States ex rel. Batiste v. SLM Corp.*, 659 F.3d 1204, 1209 (D.C. Cir. 2011)).

That is likely the case here. The Court unsealed this case at least in part because the United States "cit[ed] the existence of a similar, sealed *qui tam* action in the Middle District of Florida." *See* Doc. 8, at 1. In the government's view, that "similar, sealed *qui tam* action" is apparently analogous enough to "equip it" to investigate Zafirov's instant allegations. *See Heath*, 791 F.3d at 121. That first-filed action likely strips this Court of jurisdiction under the first-to-file bar.

That the other case remains under seal does not change the analysis because sealed cases also trigger the first-to-file rule. *See United States ex rel Wilson v. Bristol-Myers Squibb, Inc.*, 750

F.3d 111, 117 (1st Cir. 2014); *United States ex rel. Bartz v. Ortho-McNeil Pharm.*, 856 F. Supp. 2d 253, 268 (D. Mass. 2012) ("[A] sealed Complaint is considered for purposes of the first-to-file bar."); *see also United States ex rel. Carter v. Halliburton Co.*, 144 F. Supp. 3d 869, 872 (E.D. Va. 2015) (acknowledging that "a sealed action . . . destroyed this Court's subject matter jurisdiction due to the first-to-file bar"). Instead of continuing under questionable jurisdiction, the Court should dismiss this case.[6]

V. Because Zafirov's case hinges on information publicly disclosed years ago, the False Claims Act's public disclosure bar requires dismissal.

The public disclosure bar is an independent reason Zafirov's complaint fails. Like the first-to-file bar, which forecloses copycat claims, the False Claims Act contains a public disclosure bar that prevents plaintiffs from bringing "parasitic lawsuits" based on publicly available information. *Cooper v. Blue Cross and Blue Shield of Fla., Inc.*, 19 F.3d 562, 565 (11th Cir. 1994) (quoting legislative history). Under the public disclosure bar, [7] the Court "shall dismiss an action or claim" whenever "substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed" in any of three ways: (1) a federal hearing in which the government is a party; (2) in a federal report, hearing, audit, or investigation; or (3) from the news media. *See* 31 U.S.C. § 3730(e)(4).

---

[6] At minimum, the Court should stay this litigation until additional information about this "similar, sealed qui tam action" is revealed. *Cf. Samson v. United HealthCare Servs., Inc.*, No. C19-0175JLR, 2020 WL 3971390, at *6–7 (W.D. Wash. July 14, 2020) (staying subsequent litigation "under the first-to-file rule due to potential issues" overlapping with the still-uncertain first action) (citing *Baatz v. Columbia Gas Transmission, LLC*, 814 F.3d 785, 795 (6th Cir. 2016)).

[7] Though Congress amended the False Claims Act's public disclosure bar in 2010, the "change is not significant." *Bellevue v. Univ. Health Servs. of Hartgrove, Inc.*, 867 F.3d 712, 718 (7th Cir. 2017) (observing that the amendment accords with the pre–existing interpretation "of this circuit and most other circuits."). The Eleventh Circuit adopted the pre-amendment public disclosure bar test, with minor modifications. *See United States ex rel. Osheroff v. Humana, Inc.*, 776 F.3d 805, 812 (11th Cir. 2015) (reaffirming the *Cooper* three–part public disclosure bar test).

The public disclosure bar "prevents opportunistic suits by private persons who heard of fraud but played no part in exposing it." *See Cooper*, 19 F.3d at 565. Under the Eleventh Circuit's three-part test, the public disclosure bar requires dismissal if: (A) "the allegations made by the plaintiff [have] been publicly disclosed," (B) that "disclosed information" is "substantially the same" as the plaintiff's allegations, and (C) the plaintiff is not "an 'original source' of that information." *See United States ex rel. Osheroff v. Humana, Inc.*, 776 F.3d 805, 812 (11th Cir. 2015). Zafirov's case is copied and pasted from old lawsuits and national media coverage; thus, this is a quintessential example of an "opportunistic suit[] by [a] private person who heard of fraud but played no part in exposing it." *Cooper*, 19 F.3d at 565.

A. Zafirov's allegations were publicly disclosed.

Under *Cooper*, the first question is "whether the allegations or transactions at issue were publicly disclosed." *Humana*, 776 F.3d at 812. Under each of the False Claim Act's three public disclosure paradigms, these allegations have been "publicly disclosed." They were discussed in (1) prior federal hearings, (2) prior federal reports, hearings, audits, and investigations, and (3) the news media.

First, these allegations appeared in a prior civil hearing in which the Government was a party. 31 U.S.C. § 3730(e)(4)(A)(i). The *Sewell* case, which Zafirov refers to in her complaint, involved indistinguishable allegations that Freedom, Optimum, Pagidipati, and others "knowingly submit[ed] incorrect and unsubstantiated risk adjustment data to CMS in order to fraudulently increase their capitation payments." *Compare United States ex rel. Sewell v. Freedom Health, Inc., et al.*, No. 8:09-cv-1625-T-35TGW (M.D. Fla.), Doc. 44, Second Am. Compl. ¶ 9 *with* Compl. ¶ 47 (Defendants caused "submission of false and unsubstantiated risk adjustment data to CMS in order to unlawfully increase their capitation payments."). Because the United States was a party

to that suit, everything it revealed was "publicly disclosed" within the meaning of the statute. *See* 31 U.S.C. § 3730(e)(4)(A)(i).

Second, these allegations were also publicly disclosed in prior government investigations, reports, and audits. 31 U.S.C. § 3730(e)(4)(A)(ii). CMS and industry groups have been in conversation about incorrect diagnosis coding for a decade. When CMS proposed RADV audits, Medicare Advantage insurers quickly made the agency aware of imperfections in risk adjustment data. This prompted CMS to create the Fee-for-Service Adjuster to account for errors. *See Azar*, 330 F. Supp. 3d at 179–80. Moreover, the challenges of ensuring accurate and complete diagnosis data are the subject of an ongoing conversation between CMS and industry groups regarding risk adjustment payment methodology. *See* CMS, *Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter* 54–56 (Apr. 2, 2018), https://www.cms.gov/MEDICARE/HEALTH-PLANS/MEDICAREADVTGSPECRATESTATS/DOWNLOADS/ANNOUNCEMENT2019.PDF; CMS, *Announcement of Calendar Year (CY) 2016 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter* 33–35 (Apr. 6, 2015), https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2016.pdf. Zafirov's Complaint does not reveal anything the government does not already know.

Third, and finally, these allegations were publicly disclosed in the news media. 31 U.S.C. § 3730(e)(4)(A)(iii). When *Sewell* ultimately settled,[8] it generated significant press coverage. *The*

[8] Importantly, the *Sewell* settlement agreement contained an express disclaimer of wrongdoing or liability. As Pagidipati stated at the time of settlement, the parties "agreed to disagree without any admission of liability to avoid the time and expense of prolonged litigation." Margie Manning, *Kiran Patel's Health Insurance Firms Agree to $32M Settlement with the Feds*,

New Yorker featured a multi-page unpacking of the *Sewell* allegations. *See* Sheelah Kolhatkar, *The Personal Toll of Whistle-Blowing,* The New Yorker, Jan. 28, 2019. "Freedom pressured doctors to schedule unnecessary appointments," *The New Yorker* revealed, "and to assign additional codes that the internal data miners thought would be more profitable." *Id. Accord* Compl. ¶ 45 (alleging Defendants "caused physicians to bring members in for medically unnecessary office visits" and "submit as many phony diagnosis codes as possible"). Other national news media covered the allegations. *See* Fred Schulte, *Medicare Advantage Insurer Settles Whistleblower Suit for $32 Million*, NPR (May 31, 2017), https://www.npr.org/sections/healthshots/2017/05/31/530868367/medicare-advantage-insurers-settle-whistleblower-suit-for-32-million. Zafirov's allegations are old news. Thus, the first prong of the *Cooper* test—"public disclosure"—is established.

B. Zafirov's allegations are substantially similar to, and often word-for-word pulled from, publicly disclosed information.

Zafirov's allegations are cut from the same cloth as the publicly disclosed information. After establishing public disclosure, *Cooper* next asks "whether the complaint's allegations are 'substantially the same' as the publicly disclosed allegations or transactions." *Humana*, 776 F.3d at 814. Because "the FCA 'is most naturally read to preclude suits based in *any part* on public[ly] disclosed information," this is not an especially demanding inquiry. *See Battle v. Bd. of Regents for Ga.*, 468 F.3d 755, 762 (11th Cir. 2006) (emphasis in original). Under this prong's "quick trigger," it is more than enough that there is "significant overlap" between the complaint and public disclosures. *Humana*, 776 F.3d at 814.

Zafirov's claims are more than substantially similar. They are often the *same*, word-for-word, as earlier public disclosures. Comparing this complaint with the *Sewell* complaint shows

---

Tampa Bay Times Journal (May 31, 2017), https://www.bizjournals.com/tampabay/news/2017/05/31/kiran-patel-s-health-insurance-firms-agree-to-32m.html.

that the core claims (that insurance providers, providers, and physicians improperly inflated capitation payments) and defendants (including Optimum, Freedom, and Pagidipati) in the two lawsuits are the same. A side-by-side comparison of the two complaints underscores just how much Zafirov took from *Sewell*.

Sewell Second Amended Complaint	**Zafirov's Current Complaint**
Defendants "knowingly submit incorrect and unsubstantiated risk adjustment data to CMS in order to fraudulently increase their capitation payments" (¶ 9)	Defendants "result[ed] in the submission of false and unsubstantiated risk adjustment data to CMS in order to unlawfully increase their capitation payments" (¶ 47)
Defendants "scour medical records looking for 'missing' diagnosis codes" to submit" to CMS (¶ 109)	Defendants "scour medical records looking for 'missing' diagnosis codes" to submit to CMS (¶ 49)
Defendants "cause their physicians to bring in certain members for medically unnecessary office visits with members for the sole purpose of capturing diagnosis codes. The office visits are not . . . for the benefit of the patient. Instead, [Defendants] cause these visits to happen solely for the purpose of fraudulently increasing their risk adjustment-based reimbursement." (¶ 113)	Defendants "caused physicians to bring members in for medically unnecessary office visits for the sole purpose of capturing diagnosis codes. These visits were not for the benefit of the patient. Instead, the Defendants caused these visits to happen solely for the purpose of increasing risk adjustment-based reimbursement." (¶ 49.a).

Zafirov's allegations more than "significant[ly] overlap" with this public information. *Humana*, 776 F.3d at 814. They are virtually identical to those in *Sewell*. Simply put, this is *Sewell* redux, with Zafirov apparently hoping to reap her own bounty from practices the government has already resolved and will continue to audit through independent third parties through 2022.

C. Zafirov is not the original source of the allegations.

Finally, Zafirov cannot show she is an "original source" to avoid application of the public disclosure bar, because she has not and cannot prove that she either (1) voluntarily disclosed everything in her complaint to the government before the original public disclosure (*e.g.*, *Sewell*) or (2) has "independent" knowledge which "materially adds" to the public disclosures *and* that she has voluntarily provided all such information to the government before filing this action. 31 U.S.C. § 3730(e)(4)(B).

As such, because each and every prong of the *Cooper* public disclosure test is satisfied, this Court should dismiss the complaint.

VI. The government action bar blocks Zafirov's case.

As another basis for dismissal, the False Claims Act's "government action bar" blocks *qui tam* suits "based upon allegations or transactions which are the subject of a civil suit or an administrative civil money penalty proceeding in which the Government is already a party." *See* 31 U.S.C. § 3730(e)(3) (the government action bar). For these purposes, an action is "based upon" an earlier government-related action "if the relator's case is receiving support, advantage, or the like from the 'host' case . . . ." *Sturgeon v. Pharmerica Corp.*, 438 F. Supp. 3d 256, 262 (E.D. Pa. 2020) (internal quotation marks and citations omitted). Because the "inquiry is essentially a test of factual similarity," courts look "for signs of a host/parasite relationship" between the earlier action and later one. *Id.* (quotation omitted). In a nutshell, "[i]f a relator's allegations are the same" as already-made allegations, "or are similar enough to be characterized as feeding off the government's allegations, the government action bar applies." *Id.* "Piggy-back *qui tam* lawsuits," like this one, which "seek[] to remedy 'fraud' arising from a situation previously addressed by the

government," cannot clear the government action bar. *See United States ex rel. Stone v. AmWest Sav. Ass'n*, 999 F. Supp. 852, 855–56 (N.D. Tex. 1997).

Sewell triggers the government action bar. "If an allegation of fraud has already been made" in the earlier government-involved action, "the analysis is straightforward." *See United States ex rel. Absher v. Momence Meadows Nursing Ctr., Inc.*, 764 F.3d 699, 708 (7th Cir. 2014). Zafirov pulls her allegations wholesale from *Sewell*, making her case a textbook "parasite" to *Sewell*'s "host." *Sturgeon*, 438 F. Supp. 3d at 262. The whole point of the government action bar is to forestall "parasitic *qui tam* lawsuits that receive support from an earlier case without giving the government any useful return," beyond "additional monetary recovery." *Pacult v. Walgreen Co.*, No. 08-cv-542-SLC, 2011 WL 13209584, at *10 (W.D. Wis. June 14, 2011) (observing that there is "no useful return to the government" if, as here, the "government decline[s] to intervene in [the] second qui tam action"). Because that is precisely the case here, Zafirov's case fails.

Leave to Amend Would Be Futile

As explained repeatedly above, allowing Zafirov to amend the complaint will not fix her lack of knowledge. Relators like Zafirov who observe allegedly improper practices but are not involved in submitting claims lack the knowledge of corporate billing and claims processing required to state a False Claims Act violation. *See Klusmeier v. Bell Constructors, Inc.*, 469 F. App'x 718, 721 (11th Cir. 2012) (holding that relators that observe contract violations but do not have first-hand knowledge of billing practices "lack the type of knowledge that normally will support an FCA complaint"). Because Zafirov has left FMA, and because her role while there did not involve claim submission, she cannot cure the fact that she has no personal knowledge of payment and billing practices. *See Seal 1*, 429 F. App'x at 820 (stating that failure to allege "any personal knowledge of the payment terms or billing practices . . . . is fatal to [a] FCA complaint");

see also United States ex rel. Shurick v. Boeing Co., 330 F. App'x 781, 784 (11th Cir. 2009) (affirming dismissal of FCA complaint because relator "lack[ed] personal knowledge of the invoices and fails to allege facts that establish that invoices were actually submitted to the government"). Zafirov is hoping to get around her lack of knowledge with discovery. But "[t]he particularity requirement of Rule 9 is a nullity if Plaintiff gets a ticket to the discovery process without identifying a single claim." *United States ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1359 (11th Cir. 2006) (quotation omitted). Zafirov should not be allowed to impose the burden and expense of discovery on Defendants in an attempt to cure her lack of knowledge. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 560 (2007). For this reason, dismissal should be with prejudice. *See United States ex rel. McFarland v. Florida Pharmacy Solutions*, 358 F. Supp. 3d 1316, 1331 (M.D. Fla. 2017) (dismissing False Claims Act complaint with prejudice where pleadings showed that the relator "lacks both specific knowledge about the submission of a consultation claim and access to information about a physician's submission of a consultation claim").

CONCLUSION

For all of the foregoing reasons, the Provider Defendants respectfully submit that Zafirov's Complaint should be dismissed with prejudice.

Dated: September 23, 2020

Respectfully submitted,

/s/ A. Lee Bentley, III

A. Lee Bentley III
Florida Bar No. 1002269
Jason P. Mehta
Florida Bar No. 106110
Kyle W. Robisch
Florida Bar No. 113089
BRADLEY ARANT BOULT CUMMINGS LLP
100 North Tampa Street, Suite 2200
Tampa, Florida 33602
Tel: (813) 559-5500
Facsimile: (813) 229-5946
Primary E-mail: lbentley@bradley.com
Primary E-mail: jmehta@bradley.com
Primary E-Mail: krobisch@bradley.com
Secondary E-Mail: dmills@bradley.com

Counsel for Defendants Florida Medical Associates, LLC, Physician Partners, LLC, Physician Partners Specialty Services, LLC, Sun Labs USA, Inc., Anion Technologies, LLC

CERTIFICATE OF SERVICE

I hereby certify that on September 23, 2020, I filed the foregoing with the Court's electronic filing system, which will cause a copy to be served upon all counsel of record.

/s/ A. Lee Bentley, III
OF COUNSEL

EXHIBIT A

CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
FREEDOM HEALTH INC. AND OPTIMUM HEALTHCARE, INC.

I. PREAMBLE

Freedom Health, Inc. and Optimum Healthcare, Inc. (collectively or individually, "Freedom") hereby enter into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). Contemporaneously with this CIA, Freedom is entering into a Settlement Agreement with the United States.

Freedom represents that, prior to the execution of this CIA, Freedom established a Compliance Program that includes, among other things, a Compliance Officer, Compliance Committee, written standards of conduct, compliance education and training, a mechanism for individuals to report incidents of non-compliance, screening programs for ineligible persons, and removal requirements for ineligible persons.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Freedom under this CIA shall be five years from the effective date of this CIA. The "Effective Date" shall be the date on which the final signatory of this CIA executes this CIA. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

B. Sections VII, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) Freedom's final Annual Report or (2) any additional materials submitted by Freedom pursuant to OIG's request.

C. For purposes of this CIA, the term "Covered Persons" means: (1) all owners who are natural persons and have an ownership interest of 5% or more, officers directors, and employees of Freedom; and (2) all contractors, subcontractors, agents, and

other persons who furnish patient care items or services or who perform billing, coding, or risk-adjustment data functions on behalf of Freedom. Covered Persons do not include active Medicare providers who are not employees of Freedom or Global TPA, LLC.

III. CORPORATE INTEGRITY OBLIGATIONS

Freedom shall establish and maintain a Compliance Program that includes the following elements:

A. Compliance Officer and Committee, Board of Directors, and Management Compliance Obligations

1. *Compliance Officer*. Within 90 days after the Effective Date, Freedom shall appoint a Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be an employee and a member of senior management of Freedom, shall report directly to the Chief Executive Officer of Freedom, and shall not be or be subordinate to the General Counsel or Chief Financial Officer or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for Freedom. The Compliance Officer shall be responsible for, without limitation:

a. developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements;

b. making periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Freedom and shall be authorized to report on such matters to the Board of Directors at any time. Written documentation of the Compliance Officer's reports to the Board of Directors shall be made available to OIG upon request; and

c. monitoring the day-to-day compliance activities engaged in by Freedom as well as any reporting obligations created under this CIA.

Any noncompliance job responsibilities of the Compliance Officer shall be limited and must not interfere with the Compliance Officer's ability to perform the duties outlined in this CIA.

Freedom shall report to OIG, in writing, any changes in the identity of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within five days after such a change.

2. *Compliance Committee*. Within 90 days after the Effective Date, Freedom shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as billing, clinical, human resources, audit, and operations). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of Freedom's risk areas and shall oversee monitoring of internal and external audits and investigations). The Compliance Committee shall meet at least quarterly. The minutes of the Compliance Committee meetings shall be made available to OIG upon request.

Freedom shall report to OIG, in writing, any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

3. *Board of Directors Compliance Obligations.* The Board of Directors (or a committee of the Board) of Freedom (Board) shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements and the obligations of this CIA. The Board must include independent (i.e., non-executive) members.

The Board shall, at a minimum, be responsible for the following:

a. meeting at least quarterly to review and oversee Freedom's compliance program, including but not limited to the performance of the Compliance Officer and Compliance Committee;

b. submitting to OIG a description of the documents and other materials it reviewed, as well as any additional steps taken, such as the engagement of an independent advisor or other third party resources, in its oversight of the compliance program and in support of making the resolution below during each Reporting Period; and

c. for each Reporting Period of the CIA, adopting a resolution, signed by each member of the Board summarizing its review and oversight of Freedom's compliance with Federal health care program requirements and the obligations of this CIA.

d. for each Reporting Period of the CIA, the Board shall retain an individual or entity with expertise in compliance with Federal health care program requirements (Compliance Expert) to perform a review of the effectiveness of Freedom's Compliance Program (Compliance Program Review). The Compliance Expert shall create a work plan for the Compliance Program Review and prepare a written report about the Compliance Program Review. The written report (Compliance Program Review Report) shall include a description of the Compliance Program Review and any recommendations with respect to Freedom's compliance program. The Board shall review the Compliance Program Review Report as part of its review and oversight of Freedom's compliance program. A copy of the Compliance Program Review report shall be provided to OIG in each Annual Report submitted by Freedom. In addition, copies of any materials provided to the Board by the Compliance Expert, along with minutes of any meetings between the Compliance Expert and the Board, shall be made available to OIG upon request.

At minimum, the resolution shall include the following language:

> "The Board of Directors has made a reasonable inquiry into the operations of Freedom's Compliance Program, including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, Freedom has implemented an effective Compliance Program to meet Federal health care program requirements and the obligations of the CIA."

If the Board is unable to provide such a conclusion in the resolution, the Board shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to implement an effective Compliance Program at Freedom.

Freedom shall report to OIG, in writing, any changes in the composition of the Board, or any actions or changes that would affect the Board's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

4. *Management Certifications.* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Freedom employees (Certifying Employees) are expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable Freedom department is in compliance with applicable Federal health care program requirements and the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: Chief Executive Officer, Chief Financial Officer, Vice President of Claims, Vice President of Enrollment, Compliance Officer, Vice President of Medicare Revenue Management, Vice President of Network Operations and Business Development, Senior Vice President of Operations, Vice President of Sales, and Chief Medical Officer. For each Reporting Period, each Certifying Employee shall sign a certification that states:

> "I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert name of department], an area under my supervision. My job responsibilities include ensuring compliance with regard to the [insert name of department] with all applicable Federal health care program requirements, obligations of the Corporate Integrity Agreement, and Freedom policies, and I have taken steps to promote such compliance. To the best of my knowledge, the [insert name of department] of Freedom is in compliance with all applicable Federal health care program requirements and the obligations of the Corporate Integrity Agreement. I understand that this certification is being provided to and relied upon by the United States."

If any Certifying Employee is unable to provide such a certification, the Certifying Employee shall provide a written explanation of the reasons why he or she is unable to provide the certification outlined above.

Within 120 days after the Effective Date, Freedom shall develop and implement a written process for Certifying Employees to follow for the purpose of completing the certification required by this section (e.g., reports that must be reviewed, assessments that must be completed, sub-certifications that must be obtained, etc. prior to the Certifying Employee making the required certification).

B. Written Standards

Within 120 days after the Effective Date, Freedom shall develop and implement written policies and procedures regarding the operation of its compliance program, including the compliance program requirements outlined in this CIA and Freedom's compliance with Federal health care program requirements (Policies and Procedures). Throughout the term of this CIA, Freedom shall enforce its Policies and Procedures and shall make compliance with its Policies and Procedures an element of evaluating the performance of all employees. The Policies and Procedures shall be made available to all Covered Persons.

At least annually (and more frequently, if appropriate), Freedom shall assess and update, as necessary, the Policies and Procedures. Any new or revised Policies and Procedures shall be made available to all Covered Persons.

All Policies and Procedures shall be made available to OIG upon request.

C. Training and Education

1. *Training Plan.* Within 120 days after the Effective Date, Freedom shall develop a written plan (Training Plan) that outlines the steps Freedom will take to ensure that: (a) all Covered Persons receive at least annual training regarding Freedom's CIA requirements and Compliance Program and Federal health care program requirements including the requirements of the Anti-Kickback Statute and the Stark Law.

The Training Plan shall include information regarding the following: training topics, categories of Covered Persons required to attend each training session, length of the training session(s), schedule for training, and format of the training. Freedom shall furnish training to its Covered Persons pursuant to the Training Plan during each Reporting Period.

2. *Board Member Training.* Within 120 days after the Effective Date, each member of the Board of Directors shall receive at least two hours of training. This training shall address the corporate governance responsibilities of board members, and the responsibilities of board members with respect to review and oversight of the Compliance Program. Specifically, the training shall address the unique responsibilities of health care Board members, including the risks, oversight areas, and strategic approaches to conducting oversight of a health care entity. This training may be conducted by an outside compliance expert hired by the Board and should include a discussion of the OIG's guidance on Board member responsibilities.

New members of the Board of Directors shall receive the Board Member Training described above within 30 days after becoming a member or within 120 days after the Effective Date, whichever is later.

3. *Training Records*. Freedom shall make available to OIG, upon request, training materials and records verifying that Covered Persons and Board members have timely received the training required under this section.

D. Review Procedures

1. *General Description*

a. *Engagement of Independent Review Organization*. Within 120 days after the Effective Date, Freedom shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform the reviews listed in this Section III.D. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

b. *Retention of Records*. The IRO and Freedom shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Freedom) related to the reviews.

2. *Conditional Provider and Facility Network Review*. In the event that Freedom, during the term of this CIA, expands its service area under an existing Medicare Advantage contract or enters into a new Medicare Advantage contract with CMS, the IRO shall confirm the accuracy of the data submitted to CMS and shall prepare a Network Review Report, as outlined in Appendix B to this CIA, which is incorporated by reference.

3. *Risk Adjustment Review*. The IRO shall conduct a Risk Adjustment Review and shall prepare a Risk Adjustment Review Report, as outlined in Appendix C to this CIA, which is incorporated by reference. The Risk Adjustment Review shall consist of a review of Freedom's RAPS filtering logic and a chart review of a random sample of 100 risk adjusted members.

4. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to Freedom a certification that the IRO has (a) evaluated its professional independence and objectivity with respect to the reviews required under this Section III.D and (b) concluded that it is, in fact, independent and objective, in accordance with the requirements specified in Appendix A to this CIA. The IRO's certification shall include a summary of all current and prior engagements between Freedom and the IRO.

E. Risk Assessment and Internal Review Process

Within 120 days after the Effective Date, Freedom shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with Freedom's participation in the Federal health care programs, including, but not limited to, the risks associated with the development and maintenance of adequate provider networks and the submission of accurate risk adjustment and encounter data under the Part C program. The risk assessment and internal review process shall require compliance, legal, and department leaders, at least annually, to: (1) identify and prioritize risks, (2) develop internal audit work plans related to the identified risk areas, (3) implement the internal audit work plans, (4) develop corrective action plans in response to the results of any internal audits performed, and (5) track the implementation of the corrective action plans in order to assess the effectiveness of such plans. Freedom shall maintain the risk assessment and internal review process for the term of the CIA.

F. Disclosure Program

Within 120 days after the Effective Date, Freedom shall establish a Disclosure Program that includes a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Freedom's policies, conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. Freedom shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. The Disclosure Program also shall include a requirement that all of Freedom's Covered Persons shall be expected to report suspected violations of any Federal health care program requirements to the Compliance

Officer or other appropriate individual designated by Freedom. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, Freedom shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or designee) shall maintain a disclosure log and shall record each disclosure in the disclosure log within two business days of receipt of the disclosure. The disclosure log shall include a summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews.

G. Ineligible Persons

1. *Definitions*. For purposes of this CIA:

a. an "Ineligible Person" shall include an individual or entity who:

i. is currently excluded from participation in any Federal health care program; or

ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded.

b. "Exclusion List" means the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available through the Internet at http://www.oig.hhs.gov).

2. *Screening Requirements.* Freedom shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

a. Freedom shall screen all prospective Covered Persons against the Exclusion List prior to engaging their services and, as part

of the hiring or contracting process, shall require such Covered Persons to disclose whether they are Ineligible Persons.

b. Freedom shall screen all current Covered Persons against the Exclusion List within 90 days after the Effective Date and on a monthly basis thereafter.

c. Freedom shall implement a policy requiring all Covered Persons to disclose immediately if they become an Ineligible Person.

Nothing in this Section III.G affects Freedom's responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by an excluded person. Freedom understands that items or services furnished, ordered, or prescribed by excluded persons are not payable by Federal health care programs and that Freedom may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Freedom meets the requirements of Section III.G.

3. *Removal Requirement.* If Freedom has actual notice that a Covered Person has become an Ineligible Person, Freedom shall remove such Covered Person from responsibility for, or involvement with, Freedom's business operations related to the Federal health care program(s) from which such Covered Person has been excluded and shall remove such Covered Person from any position for which the Covered Person's compensation or the items or services furnished, ordered, or prescribed by the Covered Person are paid in whole or part, directly or indirectly, by any Federal health care program(s) from which the Covered Person has been excluded at least until such time as the Covered Person is reinstated into participation in such Federal health care program(s).

4. *Pending Charges and Proposed Exclusions.* If Freedom has actual notice that a Covered Person is charged with a criminal offense that falls within the scope of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Covered Person's employment or contract term, Freedom shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of care rendered to any beneficiary or the accuracy of any claims submitted to any Federal health care program.

H. Notification of Government Investigation or Legal Proceeding

Within 30 days after discovery, Freedom shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Freedom conducted or brought by a governmental entity or its agents involving an allegation that Freedom has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Freedom also shall provide written notice to OIG within 30 days after the resolution of the matter and a description of the findings and/or results of the investigation or proceeding, if any.

I. Overpayments

1. *Definition of Overpayment.* For purposes of this CIA, an "Overpayment" shall mean the amount of money Freedom receives or retains under any Federal health care program to which Freedom, after applicable reconciliation, is not entitled under such Federal health care program.

2. *Overpayment Policies and Procedures.* Within 120 days after the Effective Date, Freedom shall develop and implement written policies and procedures regarding the identification, quantification, and notifications and/or repayments to CMS of Overpayments received from any Federal health care program.

J. Reportable Events

1. *Definition of Reportable Event.* For purposes of this CIA, a "Reportable Event" means anything that involves:

a. a substantial Overpayment;

b. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized;

c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.G.1.a; or

d. the filing of a bankruptcy petition by Freedom.

A Reportable Event may be the result of an isolated event or a series of occurrences.

2. *Reporting of Reportable Events*. If Freedom determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Freedom shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists.

3. *Reportable Events under Section III.J.1.a. and III.J.1.b.* For Reportable Events under Section III.J.1.a and b, the report to OIG shall include:

a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions or other conduct giving rise to the Reportable Event; the period during which the conduct occurred; and the names of individuals and entities believed to be implicated, including an explanation of their roles in the Reportable Event;

b. a statement of the Federal criminal, civil or administrative laws that are probably violated by the Reportable Event, if any;

c. the Federal health care programs affected by the Reportable Event;

d. a description of the steps taken by Freedom to identify and quantify any Overpayments; and

e. a description of Freedom's actions taken to correct the Reportable Event and prevent it from recurring.

If the Reportable Event involves an Overpayment, Freedom shall report and/or repay the Overpayment, in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and 42 C.F.R. § 422.326 (and any applicable CMS guidance) and provide OIG with a copy of the notification and repayment to CMS and any related information about reporting and/or repayment.

4. *Reportable Events under Section III.J.1.c.* For Reportable Events under Section III.J.1.c, the report to OIG shall include:

a. the identity of the Ineligible Person and the job duties performed by that individual;

b. the dates of the Ineligible Person's employment or contractual relationship;

c. a description of the Exclusion List screening that Freedom completed before and/or during the Ineligible Person's employment or contract and any flaw or breakdown in the screening process that led to the hiring or contracting with the Ineligible Person;

d. a description of how the Ineligible Person was identified; and

e. a description of any corrective action implemented to prevent future employment or contracting with an Ineligible Person.

5. *Reportable Events under Section III.J.1.d.* For Reportable Events under Section III.J.1.d, the report to OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program requirements implicated.

IV. SUCCESSOR LIABILITY

In the event that, after the Effective Date, Freedom proposes to (a) sell any or all of its business, business units, or locations (whether through a sale of assets, sale of stock, or other type of transaction) relating to the furnishing of items or services that may be reimbursed by a Federal health care program, or (b) purchase or establish a new business, business unit, or location relating to the furnishing of items or services that may be reimbursed by a Federal health care program, the CIA shall be binding on the purchaser of any business, business unit, or location and any new business, business unit, or location (and all Covered Persons at each new business, business unit, or location) shall be subject to the applicable requirements of this CIA, unless otherwise determined and agreed to in writing by OIG.

If, in advance of a proposed sale or a proposed purchase, Freedom wishes to obtain a determination by OIG that the proposed purchaser or the proposed acquisition will not be subject to the requirements of the CIA, Freedom must notify OIG in writing of the proposed sale or purchase at least 30 days in advance. This notification shall include a description of the business, business unit, or location to be sold or purchased, a brief description of the terms of the transaction and, in the case of a proposed sale, the name and contact information of the prospective purchaser.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report

Within 120 days after the Effective Date, Freedom shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A, and a summary of other noncompliance job responsibilities the Compliance Officer may have;

2. the names and positions of the members of the Compliance Committee required by Section III.A;

3. the names of the Board members who are responsible for satisfying the Board of Directors compliance obligations described in Section III.A.3;

4. the names and positions of the Certifying Employees required by Section III.A.4 and a copy of Freedom's written process for Certifying Employees to follow for the purpose of completing the certification;

5. a list of the Policies and Procedures required by Section III.B;

6. the Training Plan required by Section III.C.1 and a description of the Board of Directors training required by Section III.C.2 (including a summary of the topics covered, the length of the training, and when the training was provided);

7. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A to this CIA; and (d) a certification from the IRO regarding its professional independence and objectivity with respect to Freedom;

8. a description of the risk assessment and internal review process required by Section III.E;

9. a description of the Disclosure Program required by Section III.F;

10. a description of the Ineligible Persons screening and removal process required by Section III.G;

11. a copy of Freedom's policies and procedures regarding the identification, quantification and repayment of Overpayments required by Section III.I;

12. a list of all of Freedom's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, and the location's Medicare and state Medicaid program provider number and/or supplier number(s);

13. a description of Freedom's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and

14. the certifications required by Section V.C.

B. Annual Reports

Freedom shall submit to OIG a report on its compliance with the CIA requirements for each of the five Reporting Periods (Annual Report). Each Annual Report shall include, at a minimum, the following information:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer; a current list of the Compliance Committee members, a current list of the Board members who are responsible for satisfying the Board of Directors compliance obligations, and a current list of the Certifying Employees, along with the identification of any changes made during the Reporting Period to the Compliance Committee, Board of Directors, and Certifying Employees;

2. the dates of each report made by the Compliance Officer to the Board (written documentation of such reports shall be made available to OIG upon request);

3. the Board resolution required by Section III.A.3 and a description of the documents and other materials reviewed by the Board, as well as any additional steps taken, in its oversight of the compliance program and in support of making the resolution, and a copy of the Compliance Program Review Report;

4. a list of any new or revised Policies and Procedures developed during the Reporting Period;

5. a description of any changes to Freedom's Training Plan developed pursuant to Section III.C, and a summary of any Board of Directors training provided during the Reporting Period;

6. a complete copy of all reports prepared pursuant to Section III.D and Freedom's response to the reports, along with corrective action plan(s) related to any issues raised by the reports;

7. a certification from the IRO(s), retained pursuant to Section III.D, regarding its professional independence and objectivity with respect to Freedom;

8. a description of any changes to the risk assessment and internal review process required by Section III.E, including the reasons for such changes;

9. a summary of the following components of the risk assessment and internal review process during the Reporting Period: work plans developed, internal audits performed, corrective action plans developed in response to internal audits, and steps taken to track the implementation of the corrective action plans. Copies of any work plans, internal audit reports, and corrective action plans shall be made available to OIG upon request;

10. a summary of the disclosures in the disclosure log required by Section III.F that relate to Federal health care programs, including at least the following information: a description of the disclosure, the date the disclosure was received, the resolution of the disclosure, and the date the disclosure was resolved (if applicable). The complete disclosure log shall be made available to OIG upon request;

11. a description of any changes to the Ineligible Persons screening and removal process required by Section III.G, including the reasons for such changes;

12. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.H. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

13. a description of any changes to the Overpayment policies and procedures required by Section III.I, including the reasons for such changes;

14. a summary of Reportable Events (as defined in Section III.J) identified during the Reporting Period;

15. a summary of any audits conducted during the applicable Reporting Period by any Medicare or state Medicaid program contractor or any government entity or contractor, involving a review of Federal health care program claims, and Freedom's response/corrective action plan (including information regarding any Federal health care program refunds) relating to the audit findings;

16. a description of all changes to the most recently provided list of Freedom's locations as required by Section V.A.12; and

17. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 90 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report

C. Certifications

1. *Certifying Employees.* In each Annual Report, Freedom shall include the certifications of Certifying Employees required by Section III.A.4;

2. *Compliance Officer and Chief Executive Officer.* The Implementation Report and each Annual Report shall include a certification by the Compliance Officer and Chief Executive Officer that:

a. to the best of his or her knowledge, except as otherwise described in the report, Freedom has implemented and is in compliance with all of the requirements of this CIA; and

b. he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful.

3. *Chief Financial Officer.* The first Annual Report shall include a certification by the Chief Financial Officer that, to the best of his or her knowledge, Freedom has complied with its obligations under the Settlement Agreement: (a) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (b) not to charge to or otherwise seek payment from federal or state payors for unallowable costs (as defined in the Settlement Agreement); and (c) to identify and adjust any past charges or claims for unallowable costs.

D. Designation of Information

Freedom shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. Freedom shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG:

Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, S.W.
Washington, DC 20201
Telephone: 202.619.2078
Facsimile: 202.205.0604

Freedom:

Pawan V. Shah
Compliance Officer
Freedom Health, Inc. and Optimum Healthcare, Inc.
5600 Mariner St., Ste 101
Tampa FL 33609
pvshah@freedomh.com
Telephone: 813.506.6107
Facsimile: 813.506.6179

Unless otherwise specified, all notifications and reports required by this CIA shall be made by electronic mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. Upon request by OIG, Freedom may be required to provide OIG with an electronic copy of each notification or report required by this CIA in addition to a paper copy.

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may conduct interviews, examine and/or request copies of or copy Freedom's books, records, and other documents and supporting materials, and conduct on-site reviews of any of Freedom's locations, for the purpose of verifying and evaluating: (a) Freedom's compliance with the terms of this CIA and (b) Freedom's compliance with the requirements of the Federal health care programs. The documentation described above shall be made available by Freedom to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, and/or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Freedom's owners, employees, contractors, and directors who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Freedom shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Freedom's owners, employees, contractors, and directors may elect to be interviewed with or without a representative of Freedom present.

VIII. DOCUMENT AND RECORD RETENTION

Freedom shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs and to compliance with this CIA for six years (or longer if otherwise required by law) from the Effective Date.

IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Freedom prior to any release by OIG of information submitted by Freedom pursuant to its obligations under this CIA and identified upon submission by Freedom as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Freedom shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

Freedom is expected to fully and timely comply with all of its CIA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations

As a contractual remedy, Freedom and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Freedom fails to establish, implement or comply with any of the following obligations as described in Section III:

a. a Compliance Officer;

b. a Compliance Committee;

c. the Board of Directors compliance obligations and the engagement of a Compliance Expert, the performance of a Compliance Program Review and the preparation of a Compliance Program Review Report, as required by Section III.A.3.;

d. the management certification obligations;

e. written Policies and Procedures;

f. training and education of Covered Persons and Board Members;

g. a risk assessment and internal review process;

h. a Disclosure Program;

i. Ineligible Persons screening and removal requirements;

j. notification of Government investigations or legal proceedings;

k. policies and procedures regarding the repayment of Overpayments; and

l. reporting of Reportable Events.

2. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Freedom fails to engage and use an IRO, as required by Section III.D, Appendix A, Appendix B, or Appendix C.

3. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Freedom fails to submit a complete Implementation Report, Annual Report or any certification to OIG in accordance with the requirements of Section V by the deadlines for submission.

4. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Freedom fails to submit any Network Review Report or Risk Adjustment Data Review Report in accordance with the requirements of Section III.D, Appendix B and Appendix C or fails to report and/or repay any Overpayment identified by the IRO, as required by Appendix B or Appendix C.

5. A Stipulated Penalty of $1,500 for each day Freedom fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Freedom fails to grant access.)

6. A Stipulated Penalty of $50,000 for each false certification submitted by or on behalf of Freedom as part of its Implementation Report, any Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.

7. A Stipulated Penalty of $1,000 for each day Freedom fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Freedom stating the specific grounds for its determination that Freedom has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Freedom shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after the date Freedom receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1- 6 of this Section.

B. Timely Written Requests for Extensions

Freedom may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Freedom fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three days after Freedom receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties

1. *Demand Letter*. Upon a finding that Freedom has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Freedom of: (a) Freedom's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties. (This notification shall be referred to as the "Demand Letter.")

2. *Response to Demand Letter*. Within 10 days after the receipt of the Demand Letter, Freedom shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event Freedom elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Freedom cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

3. *Form of Payment*. Payment of the Stipulated Penalties shall be made by electronic funds transfer to an account specified by OIG in the Demand Letter.

4. *Independence from Material Breach Determination*. Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Freedom has materially

breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA

1. *Definition of Material Breach.* A material breach of this CIA means:

a. repeated violations or a flagrant violation of any of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;

b. a failure by Freedom to report a Reportable Event, take corrective action, or make the appropriate refunds, as required in Section III.J;

c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or

d. a failure to engage and use an IRO in accordance with Section III.D, Appendix A, Appendix B, or Appendix C.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Freedom constitutes an independent basis for Freedom's exclusion from participation in the Federal health care programs. The length of the exclusion shall be in the OIG's discretion, but not more than five years per material breach. Upon a determination by OIG that Freedom has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Freedom of: (a) Freedom's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion. (This notification shall be referred to as the "Notice of Material Breach and Intent to Exclude.")

3. *Opportunity to Cure.* Freedom shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate that:

a. the alleged material breach has been cured; or

b. the alleged material breach cannot be cured within the 30 day period, but that: (i) Freedom has begun to take action to cure the material breach; (ii) Freedom is pursuing such action with

due diligence; and (iii) Freedom has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter*. If, at the conclusion of the 30 day period, Freedom fails to satisfy the requirements of Section X.D.3, OIG may exclude Freedom from participation in the Federal health care programs. OIG shall notify Freedom in writing of its determination to exclude Freedom. (This letter shall be referred to as the "Exclusion Letter.") Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of Freedom's receipt of the Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. At the end of the period of exclusion, Freedom may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights*. Upon OIG's delivery to Freedom of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Freedom shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter. The procedures relating to the filing of a request for a hearing can be found at http://www.hhs.gov/dab/divisions/civil/procedures/divisionprocedures.html

2. *Stipulated Penalties Review*. Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Freedom was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Freedom shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders Freedom to pay Stipulated Penalties, such

Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Freedom requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be whether Freedom was in material breach of this CIA and, if so, whether:

a. Freedom cured such breach within 30 days of its receipt of the Notice of Material Breach; or

b. the alleged material breach could not have been cured within the 30 day period, but that, during the 30 day period following Freedom's receipt of the Notice of Material Breach: (i) Freedom had begun to take action to cure the material breach; (ii) Freedom pursued such action with due diligence; and (iii) Freedom provided to OIG a reasonable timetable for curing the material breach.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Freedom, only after a DAB decision in favor of OIG. Freedom's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Freedom upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Freedom may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. Freedom shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Freedom, Freedom shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

XI. EFFECTIVE AND BINDING AGREEMENT

Freedom and OIG agree as follows:

A. This CIA shall become final and binding on the date the final signature is obtained on the CIA.

B. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA.

C. OIG may agree to a suspension of Freedom's obligations under this CIA based on a certification by Freedom that it is no longer providing health care items or services that will be billed to any Federal health care program and it does not have any ownership or control interest, as defined in 42 U.S.C. §1320a-3, in any entity that bills any Federal health care program. If Freedom is relieved of its CIA obligations, Freedom shall be required to notify OIG in writing at least 30 days in advance if Freedom plans to resume providing health care items or services that are billed to any Federal health care program or to obtain an ownership or control interest in any entity that bills any Federal health care program. At such time, OIG shall evaluate whether the CIA will be reactivated or modified.

D. All requirements and remedies set forth in this CIA are in addition to and do not affect (1) Freedom's responsibility to follow all applicable Federal health care program requirements or (2) the government's right to impose appropriate remedies for failure to follow applicable Federal health care program requirements.

E. The undersigned Freedom signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatories represent that they are signing this CIA in their official capacities and that they are authorized to execute this CIA.

F. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Electronically-transmitted copies of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

ON BEHALF OF FREEDOM

/Bijal Patel/

BIJAL PATEL
Corporate Counsel

5/11/2017
DATE

/Latour Lafferty/

LATOUR "LT" LAFFERTY
Holland & Knight, LLP
Counsel for Freedom

5/11/2017
DATE

/Eduardo Suarez/

EDUARDO SUAREZ
The Suarez Law Firm, PA
Counsel for Freedom

5/11/2017
DATE

/Rachel May Zysk/

RACHEL MAY ZYSK
The Suarez Law Firm, PA
Counsel for Freedom

5/11/2017
DATE

ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

/Lisa M. Re/

LISA RE
Assistant Inspector General for Legal Affairs
Office of Inspector General
U.S. Department of Health and Human Services

5/11/17
DATE

/Sarah Kessler/

SARAH KESSLER
Senior Counsel
Office of Inspector General
U.S. Department of Health and Human Services

5/11/17
DATE

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.D of the CIA.

A. IRO Engagement

1. Freedom shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives the information identified in Section V.A.7 of the CIA or any additional information submitted by Freedom in response to a request by OIG, whichever is later, OIG will notify Freedom if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Freedom may continue to engage the IRO.

2. If Freedom engages a new IRO during the term of the CIA, that IRO must also meet the requirements of this Appendix. If a new IRO is engaged, Freedom shall submit the information identified in Section V.A.7 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by Freedom at the request of OIG, whichever is later, OIG will notify Freedom if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Freedom may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Provider and Facility Network Review and Risk Adjustment Review who have expertise in the Medicare program requirements applicable to the data or systems being reviewed;

2. assign individuals to design and select the Provider and Facility Network Review and/or Risk Adjustment Review samples who are knowledgeable about the appropriate statistical sampling techniques;

3. assign individuals to conduct any coding review portions of the IRO Review(s) who have a nationally recognized coding certification and who have maintained this certification (e.g., completed applicable continuing education requirements); and

4. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities

The IRO shall:

1. perform each Provider and Facility Network Review and/or Risk Adjustment Review in accordance with the specific requirements of the CIA;

2. follow all applicable Medicare program rules and reimbursement guidelines in making assessments in the Provider and Facility Network Review and Risk Adjustment Reviews;

3. request clarification from the appropriate authority if in doubt of the application of a particular Medicare program policy or regulation;

4. respond to all OIG inquires in a prompt, objective, and factual manner; and

5. prepare timely, clear, well-written reports that include all the information required by Appendix B and Appendix C to the CIA.

D. IRO Independence and Objectivity

The IRO(s) must perform the Provider and Facility Network Review and Risk Adjustment Reviews in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the U.S. Government Accountability Office.

E. IRO Removal/Termination

1. *Freedom and IRO.* If Freedom terminates its IRO(s) or if the IRO(s) withdraws from the engagement during the term of the CIA, Freedom must submit a notice explaining (a) its reasons for termination of the IRO(s) or (b) the IRO's reasons for its withdrawal to OIG, no later than 30 days after termination or withdrawal. Freedom must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the IRO.

2. *OIG Removal of IRO.* In the event OIG has reason to believe the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify Freedom in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. Freedom shall have 30 days

from the date of OIG's written notice to provide information regarding the IRO's qualifications, independence or performance of its responsibilities in order to resolve the concerns identified by OIG. If, following OIG's review of any information provided by Freedom regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify Freedom in writing that Freedom shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. Freedom must engage a new IRO within 60 days of its receipt of OIG's written notice. The final determination as to whether or not to require Freedom to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B

PROVIDER AND FACILITY NETWORK REVIEW

A. Provider and Facility Network Review. In the event that Freedom either expands the service area of an existing[1] Medicare Advantage contract ("Service Area Expansion") or enters into a new contract[2] with CMS for a Medicare Advantage plan ("New Contract"), an IRO shall perform all components of the Provider and Facility Network Review at the conclusion of the Reporting Period during which Freedom applied for the Service Area Expansion or New Contract. The Provider and Facility Network Review shall consist of confirmation of the accuracy of the data in Freedom's Health Services Delivery (HSD) Tables, any exception request information data provided to CMS, and Provider and Facility Directories and shall include a review of whether the sample of providers and/or facilities are under contract with Freedom to provide services to Freedom's Medicare Advantage enrollees.

1. *Definitions*. For the purposes of the Provider and Facility Network Review, the following definitions shall be used:

a. Applicable Contract: As applicable, either (1) Freedom's contract(s) for which it seeks a Service Area Expansion or (2) a New Contract.

b. Health Services Delivery (HSD) Table: Identification and details of network providers and facilities within the full service area of a Medicare Advantage Contract ID.[3]

c. Network Population: Providers and/or facilities for which Freedom identified as in-network for the Applicable Contract based upon the data in Freedom's Health Services Delivery (HSD) Tables, any exception request information data provided to CMS, and Provider and Facility Directories.

2. *HSD Tables and Provider Directories*. The IRO shall obtain from Freedom HSD Tables, exception requests submitted to CMS, and Provider and/or Facility Directories for each Applicable Contract.

3. *Network Review Sample*. The IRO will identify a random sample of 100 providers/facilities from the Network Population (Network Review Sample(s)) and determine the accuracy of the provider/facility information contained in the sample and to

[1] "Existing" contract includes those held by Freedom at the Effective Date of the CIA.

[2] For purposes of this Appendix B, a renewal of an existing contract will not be considered a new contract.

[3] For purposes of this Appendix B, HSD Tables submitted for IRO review may include any exception requests submitted to CMS and related material.

verify that each provider/facility was under contract with Freedom to provide services to enrollees in the plan with the Applicable Contract. Any provider/facility for which Freedom cannot produce documentation sufficient to support that the provider/facility was in Freedom's contracted network for the Applicable Contract and correctly identified in the HSD Table and Provider and/or Facility Directory shall be promptly corrected or removed from the HSD Table and Provider and/or Facility Directory.

a. Use of First Samples Drawn. For the purposes of the Network Review Sample, the first set of providers/facilities selected shall be used (i.e., it is not permissible to generate more than one list of random samples and then select one for use with the Network Review Sample(s)).

4. *Other Requirements.*

a. Supplemental Materials. The IRO shall request all documentation and materials required for its Provider and Facility Network Review and Freedom shall furnish such documentation and materials to the IRO prior to the IRO initiating its review of the Provider and Facility Network. If the IRO accepts any supplemental documentation or materials from Freedom after the IRO has completed its initial review of the Provider and Facility Network (Supplemental Materials), the IRO shall identify in the Network Review Report the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the IRO gave to the Supplemental Materials in its review. In addition, the IRO shall include a narrative in the Network Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.

5. *Referral to CMS.* Freedom shall promptly notify its members of any material corrections regarding its network, if applicable, and shall promptly inform CMS of the Provider and Facility Network Review findings of its IRO. In addition, OIG, in its sole discretion, may refer any findings of the Provider and Facility Network Review (and any related work papers) received from Freedom to CMS for appropriate follow up.[4]

B. Network Review Report. The IRO shall prepare a Network Review Report as described in this Appendix for each Network Review performed. The following information shall be included in the Network Review Report.

1. *Methodology.*

[4] To the extent requested, Freedom shall submit any material reviewed by OIG directly to CMS in electronic form.

a. Provider and Facility Network. A description of the Network Population subject to the Provider and Facility Network Review.

b. Network Review Objective. A clear statement of the objective intended to be achieved by the Provider and Facility Network Review.

c. Source of Data. A description of (1) the process used to identify providers/facilities in the Network Population and (2) the specific documentation relied upon by the IRO when performing the Provider and Facility Network Review (e.g., written agreements between Freedom and the provider/facility, telephone calls with the provider/facility contacts, printouts or screenshots of maps identifying providers/facilities, electronic communication or letters between Freedom and the provider/facility contact, exception requests information provided by Freedom to CMS), CMS program rules or memoranda (including title, date, and issuance number), Medicare Managed Care Manual or bulletins (including issue, section if relevant, and date), other policies, regulations, or directives).

d. Review Protocol. A narrative description of how the Provider and Facility Network Review was conducted and what was evaluated.

e. Supplemental Materials. A description of any Supplemental Materials as required by A.4.a., above.

2. *Statistical Sampling Documentation.*

a. Documentation of the sample selection from the statistical sampling software package used (e.g., the input file, the output files, the log file of the program run).

b. A description or identification of the statistical sampling software package used by the IRO.

3. *Findings.*

a. Narrative Results.

i. A description of Freedom's provider/facility contracting system(s), including the identification, by position description, of the personnel involved in developing and maintaining Freedom's provider and facility networks.

ii. A description of controls in place at Freedom to ensure that (1) its members have sufficient access to providers/facilities identified in Freedom's Provider and/or Facility Directories; and (2) the data in Freedom's HSD Tables, Provider and/or Facility Directories, and exception requests are accurate and regularly updated consistent with CMS's requirements.

iii. A narrative explanation of the IRO's findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Provider and Facility Network Review, including the results of the Provider and Facility Network Review.

b. <u>Quantitative Results</u>.

i. Total number and percentage of instances in which the IRO determined that Freedom's provider/facility data differed from the correct provider/facility data and in which such difference resulted in a correction and/or removal from the HSD Table and/or Provider and Facility Directory.

ii. Total number and percentage of instances in which the IRO determined that a provider or facility from the Network Review Sample was not under contract for the Applicable Contract and such determination resulted in either a correction and/or removal from the HSD Table and/or Provider and Facility Directory or creation/updating of a contract between Freedom and the provider or facility.

iii. Total number and percentage of instances in which the IRO determined that Freedom did not produce documentation sufficient to support the provider/supplier data was accurate and in which such difference resulted in a correction and/or removal from the HSD Table and/or Provider and Facility Directory.

iv. Total amount of providers and facilities in the Network Review Sample that resulted in (1) correction and/or removal from the HSD Table and/or Provider and Facility Directory; and (2) creation/updating of a contract between Freedom and the provider or facility.

v. Total amount of all providers/facilities in the Network Review Sample for the Applicable Contract.

vi. Total amount of all providers/facilities in the Network Population.

vii. Error Rate in the Network Review Sample. The Error Rate shall be calculated by dividing the number of providers/facilities that were either not accurate (or were otherwise granted an exception request) or failed to be under contract with Freedom to provide services to enrollees in the plan with the Applicable Contract by the number of providers/facilities in the Network Population.

4. *Recommendations.* The Network Review Report shall include any recommendations for improvements to Freedom's network contracting system or to Freedom's controls for ensuring that providers/facilities listed in Freedom's Provider or Facility Directories are accurate and otherwise meet CMS's provider/facility access and contracting criteria, based on the findings of the Provider and Facility Network Review.

5. *Credentials.* The names and credentials of the individuals who: (1) designed the statistical sampling procedures and the review methodology utilized for the Provider and Facility Network Review and (2) performed the Provider and Facility Network Review.

APPENDIX C

RISK ADJUSTMENT REVIEW

A. Risk Adjustment Review. The IRO shall perform a Risk Adjustment Review annually in conjunction with each of the five Reporting Periods. The purpose of the Risk Adjustment Review is to determine whether Freedom properly submitted risk adjustment eligible diagnoses to CMS in accordance with CMS's rules and criteria under the Medicare Advantage Program. The Risk Adjustment Review shall consist of two components: (1) a review of Freedom's Risk Adjustment Processing System (RAPS) filtering logic ("Filter Logic Review"); and (2) a chart review of a random sample of 100 risk adjusted members ("Chart Review"); the Risk Adjustment Review shall also include recommendations for improvement. The IRO shall perform all parts of the Risk Adjustment Review.

1. *Definitions*. For the purposes of the Risk Adjustment Review, the following definitions shall be used:

a. Data Submission Period: The period during which MA organizations may submit diagnoses for CMS to use to calculate a beneficiary's risk score for a particular Payment Year; all such data must typically be received by CMS in March of the Payment Year. The Data Submission Period for the first Reporting Period under the CIA began January 1, 2016.

b. Payment Year: The calendar year following a particular Data Submission Period; final reconciliation for a Payment Year typically occurs in July of the year following the Payment Year. The first Payment Year under the CIA will correlate with the 2016 Data Submission Period.

c. Risk Adjusted Member: A Medicare Advantage (MA) plan enrollee in a Freedom MA Plan who (1) was continuously enrolled in a Freedom MA Plan from January of the Data Submission Period through January of the Payment Year; (2) had at least one risk adjustment diagnosis during the Data Submission Period that mapped to at least one HCC during the Payment Year; (3) had Non-End Stage Renal Disease status from January of the Data Submission Period through January of the Payment Year; (4) had non-hospice status from January of the Data Submission Period through January of the Payment Year; and (5) was enrolled in Medicare Part B coverage during the full Data Submission Period.

d. Population: The Population(s) shall be defined as all Risk Adjusted Members for a particular Payment Year.

e. Filtering Logic: The algorithm (regardless of whether it is fixed or variable and regardless of whether it is computerized, otherwise mechanized, or applied by hand) applied to some or all diagnoses to determine whether a particular diagnosis should be used for Medicare Advantage risk adjustment purposes.

f. CMS's Criteria for Risk Adjustment Eligible Diagnoses: As applicable for each Reporting Period, CMS's requirements for diagnoses submissions including, but not limited to, Chapter 7 of CMS's Medicare Managed Care Manual.

g. Type of Bill Codes: Three digit codes located on a claim form that describe the type of bill a provider is submitting to a payer.

h. Place of Service Codes: Two-digit codes placed on health care professional claims to indicate the setting in which a service was provided.

i. Acceptable Physician Specialty Type Codes: Codes included on CMS's published lists of acceptable physician specialty types codes.

2. *Code-Based Data Review to Ensure Compliance with CMS's Criteria for Risk Adjustment Eligible Diagnoses.* For purposes of the Risk Adjustment Review, the following shall apply:

a. Reviewing Professional Data and Code-Based Filtering of Professional Data:

i. The IRO will apply the rules in Chapter 7 of the Medicare Managed Care Manual and in CMS's Encounter Data guidance.

ii. The IRO may utilize CPT/HCPCS codes when reviewing whether Freedom's submissions were consistent with CMS's Criteria for Risk Adjustment Eligible Diagnoses.

iii. The IRO will utilize CMS's published lists of Acceptable Physician Specialty Type Codes when reviewing whether Freedom's submissions were consistent with CMS's Criteria for Risk Adjustment Eligible Diagnoses.

iv. The IRO may utilize Place of Services Codes when reviewing whether whether Freedom's submissions were consistent with CMS's Criteria for Risk Adjustment Eligible Diagnoses.

b. Reviewing Institutional Inpatient Data and Code-Based Filtering of Institutional Inpatient Data: The IRO will apply the rules in Chapter 7 of the Medicare Managed Care Manual and CMS's Encounter Data guidance and may, accordingly, utilize the institutional Type of Bill Codes when reviewing whether Freedom's submissions were consistent with CMS's Criteria for Risk Adjustment Eligible Diagnoses.

c. Reviewing Institutional Outpatient Data and Code-Based Filtering of Institutional Outpatient Data:

i. The IRO will apply the rules in Chapter 7 of the Medicare Managed Care Manual and CMS's Encounter Data guidance and may, accordingly, utilize the institutional outpatient Type of Bill Codes when reviewing whether Freedom's submissions were consistent with CMS's Criteria for Risk Adjustment Eligible Diagnoses.

ii. The IRO may utilize CPT/HCPCS codes when reviewing Freedom's filtering of encounter data.

3. *Filter Logic Review.* For each Reporting Period, the IRO shall review the filters used by Freedom's RAPS submission system for the applicable Payment Year to ensure Freedom's compliance with CMS's Criteria for Risk Adjustment Eligible Diagnoses.

a. In the event that the IRO, through its review of Freedom's filtering logic, identifies a deficiency in the filtering logic, the IRO shall confirm that: (a) Freedom remediates the filter logic that generated the deficiency; and (b) Freedom shall take appropriate corrective or remedial action, including reporting and/or returning of overpayments in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and 42 C.F.R. § 422.326 (and any applicable CMS guidance).

b. The IRO shall provide Freedom with its observations and recommendations on suggested improvements to the filtering logic consistent with section B, infra.

4. *Chart Review.* For each Reporting Period, the IRO shall randomly select and review a sample of at least 100 Risk Adjusted Members (Chart Review Samples) from the Population to ensure Freedom's compliance with CMS Criteria for Risk Adjustment Eligible Diagnoses. Through its Chart Review, the IRO should confirm, at a minimum, the following: acceptable risk adjustment provider type, source, and physician specialty were used; that dates of service are within the Data Submission Period; valid signatures and credentials; identification of the correct beneficiary; diagnoses were coded in accordance with ICD-9/10 coding guidelines; and the CMS-HCC used in payment is substantiated.

a. In the event that the IRO, through its Chart Review, identifies submitted diagnoses that were not risk adjustment eligible in accordance with CMS Criteria for Risk Adjustment Eligible Diagnoses, Freedom shall take appropriate corrective or remedial action, including reporting and/or returning of overpayments in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and 42 C.F.R. § 422.326 (and any applicable CMS guidance).

b. The IRO shall provide its observations and recommendations on suggested improvements to Freedom's policies, procedures, and/or filtering logic, as applicable, consistent with section B, infra.

5. *Documenting Correction of Previously Submitted Codes.* Freedom shall make available to OIG all documentation that reflects the reporting to CMS. OIG, in its sole discretion, may refer the findings of the Risk Adjustment Review (and any related work papers) received from Freedom to CMS or its contractor(s) for appropriate follow up.

6. *Other Requirements.*

a. Supplemental Materials. The IRO shall request all documentation and materials required for its Risk Adjustment Review and Freedom shall furnish such documentation and materials to the IRO prior to the IRO initiating its review. If the IRO accepts any supplemental documentation or materials from Freedom after the IRO has completed its initial review (Supplemental Materials), the IRO shall identify in the Risk Adjustment Review Report the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the IRO gave to the Supplemental Materials in its review. In addition, the IRO shall include a narrative in the Risk Adjustment Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.

b. Exception for Uncontrollable Circumstances. In the event of circumstances beyond Freedom's control that prevent Freedom from accessing medical records for the IRO's review, Freedom may request that the OIG allow the IRO to replace the affected Risk Adjusted Member with a new randomly selected Risk Adjustment Member. Freedom's request must include an explanation of the uncontrollable circumstances and whether any alternative records for that Risk Adjusted Member are available. If the OIG grants Freedom's request, the IRO shall include any such replacement in its Risk Adjustment Data Review Report. The decision to grant or deny any request for an exception based on uncontrollable circumstances is in the discretion of OIG and not subject to review.

c. Risk Adjusted Member's Diagnosis without Supporting Documentation. Subject to the exception for uncontrollable circumstances in Paragraph A.6.b., any diagnoses from a Risk Adjusted Member for which Freedom cannot produce supporting documentation shall be considered an error and Freedom shall delete such diagnosis per CMS's requirements. Replacement sampling for Risk Adjusted Members diagnoses with missing documentation is permitted only for uncontrollable circumstances.

d. Use of First Samples Drawn. For the purposes of the Chart Review Sample discussed in this Appendix, and subject to the uncontrollable circumstances exception in Paragraph A.6.b., the first set of Risk Adjusted Members selected shall be used (i.e., it is not permissible to generate more than one list of random samples and then select one for use in the Chart Review Sample).

B. Risk Adjustment Review Report. The IRO shall prepare a Risk Adjustment Review Report as described in this Appendix for each Risk Adjustment Review performed. The following information shall be included in the Risk Adjustment Review Report:

1. *Methodology.*

a. Risk Adjustment Review. A description of: (i) the filtering logic subject to the Filter Logic Review; and (ii) the Population subject to the Chart Review.

b. Risk Adjustment Review Objective. A clear statement of the objective intended to be achieved by each component of the Risk Adjustment Review.

c. Source of Data.

i. A description of (a) the process used to identify Freedom's filtering logic; and (b) the process used to identify the Chart Review Sample.

ii. A description of the specific documentation relied upon by the IRO when performing each component of the Risk Adjustment Review, (e.g., program rules or memoranda (including title, date, and issuance number) issued by CMS or its contractors, Medicare Managed Care Manual or bulletins (including issue, section if relevant, and date), and other policies, regulations, or directives).

d. Review Protocol. A narrative description of how the Filter Logic Review and Chart Review were conducted and what was evaluated in each.

e. Supplemental Materials. A description of any Supplemental Materials as required by A.6.a above.

2. *Statistical Sampling Documentation – Chart Review.*

a. A copy of the printout of the random numbers generated by the "Random Numbers" function of the statistical sampling software used by the IRO.

b. A description or identification of the statistical sampling software package used by the IRO.

3. *Findings.*

a. Narrative Results.

i. A description of Freedom's filtering logic, including the identification, by position description, of the personnel involved in developing and maintaining Freedom's filtering logic.

ii. A description of the external sources of risk adjustment eligible diagnoses (e.g., network primary care physician) and the identification, by position description, of Freedom personnel responsible for communicating with external sources of risk adjustment eligible diagnoses.

iii. A description of the controls in place at Freedom to ensure the accuracy and integrity of risk adjustment data submissions to CMS.

iv. A narrative explanation of the IRO's findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding each component of the Risk Adjustment Review.

b. Quantitative Results.

i. Two spreadsheets of the results of the Chart Review that include the following information for each diagnosis submitted in the Chart Review Sample:

a) Spreadsheet 1: beneficiary health insurance claim number or Medicare Beneficiary Identifier (MBI), service from date, service through date, diagnosis codes submitted, type of provider (inpatient, outpatient, or physician), and any HCC (that resulted from the diagnosis code) for each diagnoses submitted for the applicable Reporting Period.

b) Spreadsheet 2: beneficiary health insurance claim number or Medicare Beneficiary Identifier (MBI), service from date, service through date, diagnosis codes submitted, type of provider (inpatient, outpatient, or physician), and any HCC (that resulted from the diagnosis code) for each submitted diagnoses that the IRO determined was not risk adjustment eligible in accordance with CMS Criteria for Risk Adjustment Eligible Diagnoses.

ii. Error rate in the Chart Review Sample. The Error Rate shall be calculated by dividing the number of Risk Adjusted Members in the Chart Review Sample for whom Freedom submitted diagnoses that the IRO determined were not risk adjustment eligible by the number of Risk Adjusted Members in the Chart Review Sample.

4. *Recommendations*. The Risk Adjustment Review Report shall include any recommendations for improvements to Freedom's filtering logic and Freedom's controls for ensuring that risk adjustment data submitted to CMS are accurate, based on the findings of the Risk Adjustment Review.

5. *Credentials*. The names and credentials of the individuals who: (1) designed the review methodology utilized for each component of the Risk Adjustment Review and (2) performed each component of the Risk Adjustment Review.

6. *Independence and Objectivity Certification*. The IRO shall include in its report a certification that the IRO has (a) evaluated its professional independence and objectivity with respect to the reviews required under this Section III.D and (b) concluded that it is, in fact, independent and objective. The IRO's certification shall include a summary of all current and prior engagements between Freedom and the IRO.