UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

CASE NO. 19-CR-80181-RAR

UNITED STATES OF AMERICA,

v.

MINAL PATEL,

Defendant.
_____/

ORDER DENYING DEFENDANT'S MOTION TO DISMISS THE INDICTMENT

THIS CAUSE comes before the Court on Defendant Minal Patel's Motion to Dismiss the Indictment, Incorporated Memorandum of Law, and Request for Oral Argument [ECF No. 187] ("Motion"). Having reviewed the Motion, the Government's Response in Opposition [ECF No. 191], Defendant's Reply [ECF No. 194], Patel's Notice of Supplemental Authority [ECF No. 196], and being otherwise fully advised, and finding that oral argument is unnecessary to further explain the parties' respective positions, it is hereby

ORDERED AND ADJUDGED that the Motion is **DENIED** as set forth herein.

BACKGROUND

On September 24, 2019, the Government filed a thirteen-count indictment charging Patel—the owner of Georgia laboratory LabSolutions LLC—with conspiracy to commit health care fraud and wire fraud (18 U.S.C. § 1349), health care fraud (18 U.S.C. § 1347), conspiracy to defraud the United States and to pay and receive health care kickbacks (18 U.S.C. § 371), payment of kickbacks in connection with a federal health care program (42 U.S.C. § 1320a-7b(b)(2)(A)), and conspiracy to commit money laundering (18 U.S.C. § 1956(h)). *See* Indictment [ECF No. 1].

The Indictment alleges that from approximately July 2016 through August 2019, Patel participated in an illegal scheme relating to cancer genomic ("CGx") testing, which uses DNA

sequencing to detect mutations in genes that could indicate a higher risk of developing certain types of cancers in the future. *Id.* at 6. Specifically, Patel allegedly paid kickbacks to patient recruiters in exchange for referrals of Medicare beneficiaries for CGx testing, regardless of whether the tests were medically necessary. *Id.* at 10. The Indictment avers that Patel and his co-conspirators used sham contracts to disguise the kickbacks as payments for legitimate marketing services. *Id.* Under those contracts, Patel would pay the patient recruiters a percentage of the amount Medicare reimbursed for the tests. *Id.*

The patient recruiters allegedly targeted Medicare beneficiaries with telemarketing campaigns and health fairs to induce them to accept CGx tests regardless of medical necessity. *Id.* at 11. The patient recruiters then paid kickbacks to telemedicine companies in exchange for doctors' orders authorizing CGx testing for the patients, even though those doctors were not treating the beneficiaries for cancer or symptoms of cancer, did not use the test results in the treatment of the beneficiaries, did not conduct a proper telemedicine visit, and often never communicated with the beneficiaries at all. *Id.* at 11.

The Indictment contends that Patel's payments to patient recruiters in exchange for CGx testing referrals constitute illegal remuneration under the Anti-Kickback Statute ("AKS")—which prohibits the knowing and willful payment of remuneration to induce referrals for federally funded health care services. *Id.* at 15; 42 U.S.C. § 1320a-7b(b)(2)(A). The Indictment also indicates that the CGx tests were not medically necessary as required for Medicare reimbursement because they were not used to diagnose or treat Medicare beneficiaries' cancer. Indictment at 6-7. The Government relies on 42 U.S.C. § 1395y(a)(1)(A), which provides that Medicare generally does not cover items or services that are "not reasonable and necessary for the *diagnosis or treatment* of illness or injury or to improve the functioning of a malformed body member." *Id.* at 6 (quoting

42 U.S.C. § 1395y(a)(1)(A)) (emphasis added). The Government also cites 42 C.F.R. § 411.15(a)(1), which excludes from coverage

> [e]xaminations performed for a purpose other than treatment or diagnosis of a specific illness, symptoms, complaint, or injury, except for screening mammography, colorectal cancer screening tests, screening pelvic exams, prostate cancer screening tests, glaucoma screening exams, ultrasound screening for abdominal aortic aneurysms (AAA), cardiovascular disease screening tests, diabetes screening tests, a screening electrocardiogram, initial preventive physical examinations that meet the criteria specified in paragraphs (k)(6) through (k)(15) of this section, additional preventive services that meet the criteria in § 410.64 of this chapter, or annual wellness visits providing personalized prevention plan services.

Indictment at 6; 42 C.F.R. § 411.15(a)(1).

The Government maintains that Medicare does not cover cancer screening tests aside from those specifically listed in § 411.15(a)(1) and § 1395y(a)(1)(F)-(H)—*i.e.*, limited frequency mammograms, colonoscopies, pelvic exams, pap smears, and prostate exams. *See* Indictment at 6; Resp. at 10. It also avers that Medicare only covers diagnostic laboratory tests if they are "ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem." Indictment at 6 (quoting 42 C.F.R. § 410.32(a)). Section 410.32(a) further states that "[t]ests not ordered by the physician who is treating the beneficiary are not reasonable and necessary." *Id.*

In his Motion, Patel argues that the Indictment should be dismissed because it does not state a viable criminal offense. Patel contends that Medicare is required to cover any screening test that is recommended by the United States Preventive Services Task Force (USPSTF)[1]—and

[1] The USPSTF is "an independent, volunteer panel of national experts in primary care medicine that makes recommendations about clinical preventive services based on a review of existing peer-reviewed evidence." *Hohenberger v. United States*, No. 14-00337, 2015 WL 6172057, at *4 n.3 (D. Colo. Oct. 21, 2015), aff'd, 660 F. App'x 637 (10th Cir. 2016).

that the USPSTF recommends BRCA genetic testing, the type of CGx testing at issue in this case, for asymptomatic patients who have a family history, genetic susceptibility, or ancestry of BRCA-syndrome cancer. *See* Mot. at 7. Patel argues that dismissal of the Indictment is therefore warranted because it is entirely predicated on Medicare not covering CGx testing for beneficiaries who were asymptomatic or did not have cancer. *Id.* at 7, 12-16. Patel also argues that because the CGx tests are screening tests—not diagnostic tests—the Government's reliance on 42 C.F.R. § 410.32(a) (which applies to diagnostic laboratory tests) and Local Coverage Determinations (LCDs) issued by Medicare administrative contractors (which Patel claims cannot constrain coverage for preventive screening tests) is misplaced.

With respect to the kickback allegations, Patel insists that his lab's payments to patient recruiters were permissible payments to "patient navigators" under the Affordable Care Act. *See* Mot. at 18-19. Patel contends that such patient navigator programs are exempt from the prohibitions in the AKS. *Id.* Patel further argues that the Health and Human Services Office of the Inspector General (OIG) has excluded payments to promote preventative care services from the definition of "remuneration" under the AKS. *Id.* at 17-18.

Patel also argues that the Indictment should be dismissed because it is premised on Patel's laboratory submitting medically unnecessary testing, but courts have held that laboratories do not have an independent duty to determine the medical necessity of tests ordered by physicians. *Id.* at 24-26.

LEGAL STANDARD

Fed. R. Crim. P. 7(c)(1) requires that an indictment contain "a plain, concise, and definite written statement of the essential facts constituting the offense charged." Under Fed. R. Crim. P. 12(b)(1), "[a] party may raise by pretrial motion any defense, objection or request that the court can determine without a trial of the general issue." A motion alleging a defect in the indictment

must be raised before trial, unless the defect is regarding the district court's lack of jurisdiction or failure to state an offense, which may be brought at any time while a case is pending. *United States v. Baxter*, 579 F. App'x 703, 705 (11th Cir. 2014) (citing Fed. R. Crim. P. 12(b)(3)(A)-(B)).

An indictment is sufficient if it: "(1) presents the essential elements of the charged offense, (2) notifies the accused of the charges to be defended against, and (3) enables the accused to rely upon a judgment under the indictment as a bar against double jeopardy for any subsequent prosecution for the same offense." *Id.* (quoting *United States v. Steele*, 178 F.3d 1230, 1233-34 (11th Cir. 1999)). A court must determine the sufficiency of an indictment from its face and "may not dismiss an indictment based on a determination of facts that should have been developed at trial." *Id.* (citing *United States v. Salman*, 378 F.3d 1266, 1268 (11th Cir. 2004); *United States v. Sharpe*, 438 F.3d 1257, 1263 (11th Cir. 2006)).

Indeed, the Eleventh Circuit has held that there is "no summary judgment procedure in criminal cases. Nor do the rules provide for a pre-trial determination of the sufficiency of the evidence." *United States v. Critzer*, 951 F.2d 306, 307 (11th Cir. 1992); *see also Salman*, 378 F.3d at 1268 ("A motion for acquittal under Rule 29 is the proper avenue for contesting the sufficiency of the evidence in criminal cases because there is no explicit authority to grant a pre-trial judgment as a matter of law on the merits under the Federal Rules of Criminal Procedure."). An indictment that charges in the language of the relevant statute is sufficient "as long as it also provides a statement of facts and circumstances that give notice of the offense to the accused." *United States v. Jordan*, 582 F.3d 1239, 1246 (11th Cir. 2009) (quotation omitted).

ANALYSIS

The Court finds that the Indictment in this case is legally sufficient on its face and agrees with the Government that Patel's arguments are essentially an invitation for the Court to resolve a factual dispute. Further, as explained below, the Court disagrees with Patel's interpretation of

several of the statutory provisions and regulations discussed in his Motion. The Court therefore concludes that the Indictment alleges a viable criminal offense and that dismissal is not justified. The Court will address each of Patel's arguments in turn.

a. Whether dismissal is warranted based on USPSTF recommendations relating to CGx testing

Patel first argues that CGx tests are recommended by the USPSTF and that Medicare is required to cover any preventive screening tests recommended by the USPSTF. *See* Mot. at 7, 12-15. Patel cites to a USPSTF Recommendation Statement titled "Risk Assessment, Genetic Counseling, and Genetic Testing for BRCA-Related Cancer," which states the following:

> The USPSTF recommends that primary care clinicians assess women with a personal or family history of breast, ovarian, tubal, or peritoneal cancer or who have an ancestry associated with BRCA1/2 gene mutations with an appropriate brief familial risk assessment tool. Women with a positive result on the risk assessment tool should receive genetic counseling and, if indicated after counseling, genetic testing. (B recommendation) The USPSTF recommends against routine risk assessment, genetic counseling, or genetic testing for women whose personal or family history or ancestry is not associated with potentially harmful BRCA1/2 gene mutations. (D recommendation)

See id., Ex. B [ECF No. 187-1] at 2. Patel contends that the Indictment's premise that Medicare does not cover CGx testing for beneficiaries who were asymptomatic or did not have cancer is therefore incorrect and the Indictment must be dismissed for failure to state an offense.

As an initial matter, even if the Court were to accept Patel's position that Medicare is required to cover USPSTF-recommended screening tests, the question of whether the CGx tests billed by Patel fell within this USPSTF recommendation—or were otherwise billed in a manner that Medicare covers—is a factual issue that cannot be resolved on a motion to dismiss. *See United States v. Ferguson*, 142 F. Supp. 2d 1350, 1354 (S.D. Fla. 2000) ("Any issues that require consideration of the facts underlying th[e] prosecution … are not the proper subject of a pretrial motion to dismiss."). Indeed, the USPSTF recommendation on which Patel relies applies only to

women with a personal or family history of certain cancers or gene mutations and contemplates that those women receive genetic counseling before being tested. As the Government correctly notes, this USPSTF recommendation does not endorse the conduct alleged in the Indictment—namely, "paying and receiving kickbacks in exchange for the referral of Medicare beneficiaries, so that LabSolutions could bill Medicare for CGx tests, without regard to whether the beneficiaries needed the test" and often where the doctor ordering the test did not interact with the beneficiary at all. *See* Indictment at 9, 11.

Moreover, the statutory provisions and other sources on which Patel relies do not support a conclusion that Medicare is required to cover all USPSTF-recommended screening tests regardless of how they were ordered or performed. The USPSTF is an independent body whose recommendations do not dictate the scope of Medicare coverage. In fact, the Recommendation Statement for BRCA screening itself makes clear that "[r]ecommendations made by the USPSTF are independent of the US government. They should not be construed as an official position of … the US Department of Health and Human Services." Mot., Ex. B. at 11.

Patel cites certain Medicare laws that reference USPSTF recommendations, but none of those statutory provisions indicate that Medicare is required to cover all USPSTF-recommended screening tests. Generally, Medicare does not cover services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). Thus, legislation has historically been required to add Medicare coverage of a service that is purely preventive, and "Medicare law has been amended numerous times to add coverage of specified preventive services . . . ." Cong. Research Serv., R40978, Medicare Coverage of Clinical Preventive Services (2010) at 4. In 2008, Congress enacted the Medicare Improvements for Patients and Providers Act (MIPPA), which authorizes the Department of Health and Human Services (HHS) to administratively extend

Medicare coverage to USPSTF-recommended services that are "reasonable and necessary" and "appropriate" for Medicare beneficiaries. P.L. 110-275 § 101; 42 U.S.C. § 1395x(ddd). However, Patel does not contend that Congress or HHS has expressly added Medicare coverage for CGx testing.

Instead, Patel insists that Medicare is required to cover CGx testing based on provisions in the Affordable Care Act ("ACA") designed to increase access to preventive services. Specifically, Patel relies on sections 4103, 4104, and 4105 of the ACA. Section 4103 of the ACA added Medicare coverage for an "annual wellness visit" that includes "personalized prevention plan services." *See* P.L. 111-148 § 4103; 42 U.S.C. § 1395x(hhh). The personalized prevention plan services consist of a health risk assessment and may contain additional elements listed in the statute, including

> [t]he establishment of . . . [a] screening schedule for the next 5 to 10 years, as appropriate, based on recommendations of the United States Preventative Services Task Force and the Advisory Committee on Immunization Practices, and the individual's health status, screening history, and age-appropriate preventive services covered under this subchapter.

This provision does not, as Patel argues, expand the scope of Medicare coverage to all USPSTF-recommended screening tests. It merely provides that USPSTF recommendations must be considered—among other factors—in the development of a beneficiary's personalized screening schedule as part of an annual wellness visit.[2] Again, to the extent Patel is arguing that the CGx tests at issue qualified for coverage based on individualized determinations made in a beneficiary's

[2] *See* Seiler et al., *Coverage of Clinical Preventive Services Under the Affordable Care Act: From Law to Access*, 129 PUBLIC HEALTH REP. 529, 530, Figure 2 (November-December 2014), *available at* https://doi.org/10.1177/003335491412900611 (indicating that under the ACA, Medicare is not required to cover all services graded A or B by the USPSTF); Ctrs. For Medicare & Medicaid Services, Medicare Claims Processing Manual, Ch. 18 § 140 ("The [Annual Wellness Visit] will include the establishment of, or update to, the individual's medical/family history, measurement of his/her height, weight, body-mass index (BMI) or waist circumference, and blood pressure (BP), with the goal of health promotion and disease detection and encouraging patients to obtain the screening and preventive services *that may already be covered and paid for under Medicare Part B*.") (emphasis added).

annual wellness visit, that is a factual dispute that is not appropriate for resolution in a motion to dismiss.

Patel's contention that the Indictment should be dismissed based on section 4104 of the ACA is similarly unavailing. Section 4104 amended 42 U.S.C. § 1395x(ddd) to define preventive services covered by Medicare to mean: the screening and preventive services listed in § 1395x(ww)(2), which do not include CGx testing; an initial preventive physical examination (IPPE); and the personalized prevention plan services that are covered pursuant to section 4103 (relating to the annual wellness visit discussed above). *See* P.L. 111-148 § 4104; Cong. Research Serv., R41196, Medicare Provisions in the Patient Protection and Affordable Care Act (PPACA): Summary and Timeline (2011) at 64. It also amended the fee schedule at 42 U.S.C. § 1395*l*(a)(1)(X) to eliminate beneficiary coinsurance requirements for most *covered* preventive services, including the personalized prevention plan services discussed in connection with the annual wellness visit. *See id.* The fee schedule at § 1395*l*(a)(1) determines how much Medicare pays for services that are covered elsewhere in the statute or applicable regulations—it does not expand the scope of services that Medicare covers as Patel suggests. *See* § 1395*l*(a)(1) (indicating that the fee schedule that follows applies only to "services with respect to which benefits are payable under this part . . .").[3]

Patel's argument that section 4105 of the ACA requires Medicare to cover any screening test recommended by USPSTF is also mistaken. *See* Reply at 11. That section authorizes the Secretary of HHS to modify the coverage of the preventive services described in 42 U.S.C. 1395x(ddd)(3)(A)—which do not include CGx testing—to the extent the modification is consistent with USPSTF recommendations. *See* P.L. 111-148 § 4105. It also allows the Secretary to withhold

[3] Similarly, the CMS materials Patel cites on page 14 of his Motion are discussing the elimination of cost-sharing for covered USPSTF-recommended services, not expanding the scope of Medicare coverage to all services recommended by the USPSTF.

payment for any covered preventive services graded D by the USPSTF. *Id.* That section does not require CMS to extend coverage to any screening test recommended by the USPSTF.

Patel also contends that under the Essential Health Benefit requirements set forth in section 1302 of the ACA, Medicare must cover "preventive and wellness services," which includes CGx testing. *See* Mot. at 3. However, "the ACA's provisions regarding . . . essential health benefits do not apply to Medicare recipients." *Libby v. Price*, 689 F. App'x 659, 660 (2d Cir. 2017) (citing 42 U.S.C. § 300gg-6; *id.* § 300gg-91(b)(2)).

In sum, the statutory provisions on which Patel relies do not support a finding that Medicare is required to cover all USPSTF-recommended tests regardless of the manner in which they were ordered or performed—and whether the particular CGx tests Patel's laboratory billed were appropriate for coverage is a factual issue that cannot be resolved on a motion to dismiss.

b. Whether the Indictment is deficient because it relies on diagnostic testing regulations and Medicare Administrative Contractors' LCDs

Patel contends that "[t]he Indictment's use of diagnostic laboratory testing regulations for USPSTF-recommended cancer screening tests results in a fatal legal deficiency in the Indictment." Mot. at 8. Specifically, Patel argues that because the CGx tests do not diagnose cancer but rather screen for genetic susceptibility to it, the requirements in 42 C.F.R. § 410.32(a) do not apply. *Id.* at 3. Although Patel is correct that § 410.32(a) relates to diagnostic testing, he overstates the role of this regulation in the Government's legal theory. The Indictment alleges that aside from certain exceptions expressly spelled out in applicable statutes or regulations—such as screening mammography, colorectal cancer screening tests, screening pelvic exams, and prostate cancer screening tests—Medicare does not cover preventive or screening tests at all. *See* Indictment at 6. The Indictment then alleges that *if* the testing at issue *was* ordered for diagnosing or treating an illness, it would have to meet additional requirements that the CGx tests billed by Patel's laboratory did not meet, including those set forth in § 410.32(a). *Id.* The Government's case does not turn

on whether CGx tests qualify as diagnostic tests under § 410.32(a)—and its reference to this regulation is not a fatal legal deficiency in the Indictment as Patel posits.

Patel also argues that "the Indictment misstates Medicare Administrative Contractors authority to enact coverage guidelines for preventive services under federal law." Mot. at 20. He insists that "Local Coverage Determinations ('LCDs') may only contain *diagnostic* coverage guidelines that are reasonable and medically necessary for the treatment of an illness or injury" and that "[a]n LCD may not contain coverage of preventive services because Medicare Administrative Contractors have no authority to enact coverage of preventive services as a matter of law." *Id.* at 21. For purposes of the present Motion, the Court finds it unnecessary to delve into the scope of Medicare Administrative Contractors' ("MACs") authority to issue LCDs. All the Indictment says about MACs is that they "were private entities that reviewed claims and made payments to providers for services rendered to Medicare beneficiaries" and that they "were responsible for processing Medicare claims arising within their assigned geographical area, including determining whether the claim was for a covered service." Indictment at 3. The Indictment does not rely on coverage limitations imposed by MACs in LCDs (indeed, the Indictment does not reference any LCDs), but rather relies on coverage limitations set forth in Medicare statutes and regulations. The authority of MACs to issue LCDs relating to preventive screening services is therefore not pertinent to the issue of whether the Indictment states a viable offense.

Further, the Court does not see anything in the language of section 13.5.4 of the Medicare Program Integrity Manual cabining LCDs to diagnostic testing as Patel argues. *See* Mot. at 21. It appears that Patel is arguing that LCDs could not appropriately limit coverage for CGx testing because Medicare is statutorily required to cover such testing based on USPSTF recommendations. However, as the Court explained above, the Medicare laws that Patel cites do not categorically

mandate coverage for all USPSTF-recommended testing. Patel's arguments regarding MACs' authority to issue LCDs therefore do not provide a basis for dismissal of the Indictment.[4]

c. Whether the Indictment incorrectly applies the AKS to patient navigator programs

Patel argues that the patient recruiter compensation models alleged in the Indictment are exempt from the AKS because the patient recruiters are permissible "Patient Navigators" under federal law. Mot. at 18-19. In support of this argument, Patel cites to sections 4003-4004 of the ACA and an October 30, 2013 letter from HHS Secretary Kathleen Sebelius to Senator Jim McDermott. *Id.*; Reply at 9.

The ACA provisions Patel cites are wholly devoid of support for his position that the patient recruiters described in the Indictment were legitimate Patient Navigators and the kickbacks Patel allegedly paid them were exempt from the AKS. Section 4003 of the ACA establishes various task forces to review the effectiveness of prevention services and provide recommendations to the health care community, while section 4004 of the ACA requires the Secretary of HHS to establish a public-private partnership to conduct a prevention and health promotion outreach campaign. *See* P.L. 111-148 §§ 4003-04. Neither of these provisions bears any relation to, much less authorizes, the conduct alleged in the Indictment—that is, paying patient recruiters to refer Medicare beneficiaries for tests that are not covered by Medicare and seeking reimbursement from Medicare for those tests.

Patel argues that in the October 30, 2013 letter to Senator McDermott, Secretary Sebelius "provided written guidance … clarifying HHS's exemption of ACA patient navigator programs

[4] While on the topic of LCDs, the Court notes that the LCDs and Local Coverage Articles ("LCA") Patel cites do not support dismissal of the Indictment. In support of his position that Medicare covers CGx testing for asymptomatic beneficiaries, Patel points to LCDs and LCAs from two MACs, Novitas and Palmetto LCA, which indicate that procedure codes for CGx testing are not required to be paired with a diagnosis code in a claim for payment. *See* Mot. at 22-23. The Court agrees with the Government that such billing instructions do not establish the scope of Medicare coverage.

that promote USPSTF preventive services from enforcement under the Federal Anti-Kickback Statute." Mot. at 9. In that letter, the Secretary indicates that "Navigators for the Federally-facilitated Marketplaces and other federally funded consumer assistance programs" are not considered "federal health care programs" under 42 U.S.C. 1320a–7b(f). The letter's reference to "Navigators" is thus in the context of the insurance plan marketplace established by the ACA where individuals can sign up for health insurance plans. Such Navigators assist consumers in purchasing health insurance from state and federal health care exchanges. *See* 42 U.S.C. § 18031(i). The letter does not discuss patient navigator programs that promote USPSTF preventive services—and certainly does not address payment arrangements between laboratories and patient recruiters who recruit Medicare beneficiaries for testing.

There is an ACA provision discussing "patient navigators," section 3510, which reauthorized the "patient navigator grants" established in section 340A of the Public Health Service Act (42 U.S.C. § 256a). *See* P.L. 111-148 § 3510. However, "patient navigator" is a defined term under federal law, which refers to "an individual who has completed a training program approved by the Secretary to perform the duties" specified in the statute. *See* 42 U.S.C. § 256a(*l*)(3). None of the facts alleged in the Indictment support Patel's position that the patient recruiters he allegedly paid for referrals were patient navigators under federal law.

d. Whether the payment arrangements described in the Indictment are exempt from the AKS because they are payments to promote preventive services

Relying on 70 Fed. Reg. 4873 and 42 C.F.R. § 1003.110, Patel contends that OIG has excluded payments to promote preventive care services from the definition of "remuneration" under the AKS. However, neither of these provisions support dismissal of any of the counts in the Indictment. Section 1003.110 provides that *for purposes of 42 C.F.R. 1003.1000(a)*—which relates to civil monetary penalties laws for inducements offered to beneficiaries—"remuneration" is defined to exclude "incentives given to individuals to promote the delivery of preventive care

services where the delivery of such services is not tied (directly or indirectly) to the provision of other services reimbursed in whole or in part by Medicare or an applicable State health care program." 42 C.F.R. § 1003.110. It then defines "preventive care services" as a prenatal service, post-natal well-baby visit, or a specific clinical service recommended by USPSTF that is reimbursable by Medicare or a state health care program. *Id.*

There are several reasons why this regulation does not justify dismissal of the Indictment. First, its definition of remuneration is only applicable in the context of civil monetary penalty regulations. It does not speak to the definition of remuneration in the context of the criminal AKS. Second, the exemption relates to prohibitions against *beneficiary* inducements, whereas the Indictment alleges that Patel paid kickbacks to patient recruiters. Third, the definition of "preventive care services" is specifically limited to those USPSTF-recommended services that are *covered* by Medicare or a state health care program. As discussed above, the Court disagrees with Patel's position that Medicare categorically covers any service recommended by the USPSTF—and whether the CGx tests Patel ordered were covered is a factual issue to be resolved by a jury.

For essentially the same reasons, 70 Fed. Reg. 4873 does not support dismissal of the Indictment. That provision appears in an OIG notice containing "Supplemental Compliance Program Guidance for Hospitals." It indicates that the prohibition against beneficiary inducements in the Civil Monetary Penalty Law, 42 U.S.C. § 1320a-7a(a)(5), does not apply to incentives offered to promote the delivery of certain preventive care services—specifically, a prenatal service, post-natal well-baby visit, or a specific clinical service recommended by the USPSTF "*that is reimbursed by Medicare or Medicaid*." 70 Fed. Reg. 4873 (emphasis added). Thus, like section 1003.110, it is also addressing the meaning of remuneration in the context of civil monetary penalties laws, beneficiary inducements, and with respect to the specific preventive services that are covered by Medicare. This notice does provide some general guidance on OIG's chief

kickback concerns in the context of beneficiary inducements, but it does not address the types of kickback arrangements alleged in the Indictment or carve out exceptions from the criminal AKS's definition of remuneration.

e. Whether dismissal is appropriate because laboratory owners do not have an independent duty to determine medical necessity

Patel argues that the Indictment is legally flawed because it alleges that Patel's laboratory was responsible for determining the medical necessity of the tests ordered by physicians prior to submitting claims to Medicare. *See* Mot. at 24-25. Patel cites to several civil False Claims Act cases where courts have clarified that laboratories are not required to independently determine the medical necessity of tests ordered by physicians. *See id.* (citing *United States v. Boston Heart Diagnostic Corp.*, 296 F. Supp. 3d 155 (D.D.C. 2017) ("*Boston Heart*"); *United States ex. Rel Riedel v. Boston Heart Diagnostic Corp.*, 332 F. Supp. 3d 48, 56 (D.D.C. 2018) ("*Riedel*"); *United States v. Lab'y Corp. of Am. Holdings*, No. 14-03699, 2019 WL 236799, at *2 (D.S.C. Jan. 16, 2019)).

However, as the Government correctly states, these cases also make clear that "laboratories have a legal duty to ensure that they do not submit claims for medically unnecessary tests," *Boston Heart*, 296 F. Supp. 3d at 166, and that laboratories may be held liable for fraud if they encourage the ordering of medically unnecessary testing. *See id.* ("In this case, the relator has sufficiently alleged that Boston Heart submitted false claims by engaging in a scheme that encouraged non-cardiology physicians to order medically unnecessary tests, and then billing the Government for those tests."); *Riedel*, 332 F. Supp. 3d at 70 ("[I]mproper inducements such as providing kickbacks or promoting medically unnecessary testing is a violation of the False Claims Act.") (internal quotation and citation omitted); *Lab'y Corp. of Am. Holdings*, 2019 WL 236799 at *3 ("[T]here can still be a [False Claims Act] violation where a laboratory engages in a scheme to encourage physicians to order medically unnecessary tests.") (quotation and alterations omitted). Thus, these

cases do not stand for the proposition that a laboratory owner is immune from civil or criminal liability in a scheme designed to bill Medicare for medically unnecessary testing.

CONCLUSION

For the foregoing reasons, Patel's Motion to Dismiss the Indictment [ECF No. 187] is **DENIED**.

DONE AND ORDERED in Fort Lauderdale, Florida, this 22nd day of June, 2021.

RODOLFO A. RUIZ II
UNITED STATES DISTRICT JUDGE