IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

UNITED STATES OF AMERICA	*	
v.	*	**CRIMINAL NO. JKB-22-0146**
RON ELFENBEIN,	*	
Defendant.	*	

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MEMORANDUM

Pending before the Court is Defendant Ron Elfenbein's Motion for Judgment of Acquittal or, in the Alternative, for a New Trial. (ECF No. 78.)[1] In this case, the Government was required to prove that certain allegedly fraudulent statements were in fact false, separate and apart from the Defendant's intent. The record in this case lacks evidence from which a reasonable jury could find that those statements were false beyond a reasonable doubt. Accordingly, the Court will grant the Defendant's Motion for Judgment of Acquittal. Further, because the evidence weighs so heavily against the verdict, the Court will also conditionally grant the Defendant's alternative Motion for a New Trial.

Under the relevant law, the Defendant is not guilty, and he will be discharged.

I. Factual and Procedural Background

On August 4, 2023, a jury convicted the Defendant on all five counts of the Amended Superseding Indictment ("Indictment"). The Indictment alleged that the Defendant:

> [D]id knowingly and willfully execute and attempt to execute a scheme to defraud a health care benefit program affecting commerce, . . . that is, Medicare, Medicaid, TRICARE, Commercial Insurers, and the HRSA COVID-19 Uninsured Program, and to obtain and attempt to obtain, by means of materially false and fraudulent pretenses, representations, and promises, money and property owned by, and under the custody and control of Medicare, Medicaid, TRICARE, Commercial Insurers, and the HRSA COVID-19 Uninsured Program, in violation of Title 18, United States Code, Sections 1347 and 2 (hereinafter the "scheme to defraud").

(Indictment ¶ 28, ECF No. 51.) It further alleged that the purpose of the scheme was to:

> [U]nlawfully enrich himself and others by: (a) submitting and causing the submission of false and fraudulent claims to Medicare, Medicaid, TRICARE, Commercial Insurers, and the HRSA COVID-19 Uninsured Program for E/M [evaluation and management] Services during the COVID-19 pandemic that were medically unnecessary, not provided as represented, and ineligible for reimbursement; (b) concealing the submission of false and fraudulent claims and

[1] The Defendant requested a hearing on this Motion, which the Government opposed. No hearing is necessary.

> the receipt and transfer of the proceeds of the fraud; and (c) using proceeds of the fraud for the personal use and benefit of the defendant and others.

(*Id.* ¶ 29.) The Indictment charged the Defendant with five counts, each representing an execution of the scheme. (*Id.* ¶ 31.) The Government alleged that the Defendant "submitted and caused the submission of the following false and fraudulent claims to Medicare and CareFirst Blue Cross Blue Shield for E/M Services that were medically unnecessary, not provided as represented, and ineligible for reimbursement[.]" (*Id.*) Each count represents a claim for reimbursement for a separate patient visit that occurred in 2021. (*Id.*) As will be described in more detail below, each visit was billed with the Current Procedural Terminology ("CPT") Code 99204 or 99214 (often, hereinafter, "level 4"). (*Id.*) Counts 1–3 are claims involving Medicare, and Counts 4–5 are claims involving CareFirst Blue Cross Blue Shield ("CareFirst"). (*Id.*)

Briefly, and as described in more detail below, the facts are as follows. Healthcare providers submit reimbursement claims to insurers using CPT codes. As relevant here, evaluation and management ("E/M") services are billed using codes that are meant to reflect the complexity of a visit, ranging from a level 1 (the least complex) to a level 5 (the most complex). The Defendant was the medical director of an urgent care center that submitted thousands of reimbursement claims to Medicare and CareFirst for patient encounters involving COVID-19 testing. The evidence adduced at trial generally reflects that patients were briefly seen by a provider, with face-to-face time with a provider lasting a matter of minutes; that patients were given two COVID-19 tests, a rapid test and a polymerase chain reaction ("PCR") test; and that providers received the results of the rapid test the same day and the PCR results sometime thereafter. The E/M services were overwhelmingly billed at level 4 at the direction of the Defendant. The Government contends

these patient encounters did not qualify as level 4 visits, while the Defendant argues that the evidence at trial did not establish that these visits did not qualify as level 4 visits.

The Court concludes that, because the Government failed to present sufficient evidence from which a reasonable jury could conclude beyond a reasonable doubt that the Defendant's use of the level 4 code was objectively unreasonable and therefore false, judgment of acquittal is mandated on all five counts. And, even assuming there was sufficient evidence to sustain a conviction (which there is not), the Court will conditionally grant a new trial because the evidence weighs so heavily in favor of the Defendant that it would be unjust to enter judgment against him.

A. CPT Coding

When providers submit claims to health insurers, they include CPT codes to represent the services provided to the patient. (Tr. I-91–92, Quindoza.[2]) The Centers for Medicare & Medicaid Services ("CMS") (which administers Medicare) and CareFirst accept the guidance and the code definitions in the CPT Manual. (Tr. VIII-138, Miscoe.[3]) The codes are developed by the American Medical Association ("AMA"), which annually updates and produces a manual ("CPT Manual"). (Tr. I-92, Quindoza.) There are additional sources of guidance regarding CPT coding, including from AMA and CMS, Medicare Administrative Contractors, and other entities. (Tr. I-153, Quindoza; Tr. I-154–56, Quindoza; Tr. VIII-134–36, Miscoe; Tr. VIII-138 (Miscoe testifying that CMS sometimes issues guidance that departs from the guidance in the CPT Manual).)

The CPT Manual specifies codes for "evaluation and management" or "E/M" office visits. (Tr. I-92–93, Quindoza.) An E/M service is "an examination or a visit between a doctor or other

[2] Stephen Quindoza was the Government's only expert witness. He was qualified as an expert in "Medicare; Medicare processes, rules, and regulations, including enrollment, participation, the processing of claims, coverage, and procedural and diagnostic coding." (Tr. I-62.)

[3] Michael Miscoe was a Defense witness. He was qualified as an expert "in the fields of medical coding, evaluation and management coding, diagnostic coding, documentation of medical services and medical records." (Tr. VIII-133.)

practitioner and a patient." (Tr. I-93, Quindoza.) Codes 99201 through 99205 are used for new patients and codes 99211 through 99215 are used for established patients. (2020 CPT Manual at 12–14, Def. Ex. 3.) The codes represent E/M services of increasing complexity, with level 1 codes (i.e., codes 99201/99211) representing the lowest complexity visits and level 5 codes (i.e., 99205/99215) representing the highest complexity visits. (Tr. I-93, Quindoza.) Further, "the higher the last digit of the code, the more Medicare pays for these evaluation and management office visits." (Tr. I-96, Quindoza.) As will be explained below, the guidance pertaining to CPT coding changed throughout 2020 and 2021. To understand the CPT guidance in effect in 2021 at the time of the five charged encounters, the Court reviews the evolution of the guidance below.

1. 2020 CPT Manual

In 2020, the "key factors" providers[4] used to determine the appropriate CPT code for an E/M service were: (1) history, (2) examination, and (3) medical decision making (also referred to by various witnesses and exhibits as "MDM"). (2020 CPT Manual at 10.) The "history"—which includes an assessment of the present illness, a "review of systems," and past medical, family, and social history—can be problem focused, expanded problem focused, detailed, or comprehensive. (2020 CPT Manual at 10; Tr. VIII-146, Quindoza.) An "examination" can likewise be problem focused, expanded problem focused, detailed, or comprehensive. (2020 CPT Manual at 10.) Several terms relevant to determining the appropriate history and examination are not further defined in the CPT Manual. (*See* Tr. VIII-146–47 (Miscoe testifying that terms such as "brief"; "extended"; "pertinent"; "limited"; and "complete"—terms that are relevant for determining the history and examination—are not defined in the CPT Manual).) In 1995 and 1997, the AMA and CMS published guidelines that aimed to provide clarity relative to "history" and "examination."

[4] A "provider" could include a physician, a nurse practitioner, or a physician assistant. (Tr. VIII-139, Miscoe.)

(Tr. VIII-150–153, Miscoe; Tr. I-161, Quindoza.)

Medical decision making "refers to the complexity of establishing a diagnosis and/or selecting a management option as measured by" three factors: (1) "[t]he number of possible diagnoses and/or the number of management options that must be considered"; (2) "[t]he amount and/or complexity of medical records, diagnostic tests, and/or other information that must be obtained, reviewed, and analyzed"; and (3) "[t]he risk of significant complications, morbidity, and/or mortality, as well as comorbidities, associated with the patient's presenting problem(s), the diagnostic procedure(s), and/or the possible management options." (2020 CPT Manual at 11.) There are four types of medical decision making: straightforward, low complexity, moderate complexity, and high complexity. (*Id.*) To qualify as a particular level of decision making, per the 2020 CPT Manual, a visit must meet or exceed two of the three items in the below chart. (*Id.*) The terms in this chart—"minimal"; "limited"; "moderate"; "extensive"; and "multiple"—were not defined in the 2020 CPT Manual. (Tr. VIII-148–149, Miscoe.)

Number of Diagnoses or Management Options	Amount and/or Complexity of Data to be Reviewed	Risk of Complications and/or Morbidity or Mortality	Type of Decision Making
minimal	minimal or none	minimal	**straightforward**
limited	limited	low	**low complexity**
multiple	moderate	moderate	**moderate complexity**
extensive	extensive	high	**high complexity**

(2020 CPT Manual at 11.)

Novitas[5] published a scoring table, which was a tool used by the industry to determine the appropriate E/M code for patient visits. (Tr. VIII-156, Miscoe.) It provides guidance for scoring the history and examination (i.e., to guide determination of whether the history and examination

[5] Novitas is a Medicare Administrative Contractor that publishes tools to help providers determine appropriate coding levels, including for E/M visits. (Tr. IV-38, Raymond; *see also* Tr. I-155 (Quindoza testifying that guidance published by Novitas is reliable guidance).)

are problem focused, expanded problem focused, detailed, or comprehensive), and medical decision making (i.e., to guide determination regarding whether the medical decision making was straightforward, low, moderate, or high). (Def. Ex. 1.)

In the 2020 CPT Manual, the 99204 E/M code (the level 4 code for new patients), "requires these 3 key components: A comprehensive history; A comprehensive examination; Medical decision making of moderate complexity." (2020 CPT Manual at 13.) It explains: "[u]sually, the presenting problems are of moderate to high severity" and "[t]ypically, 45 minutes are spent face-to-face with the patient and/or family." (*Id.*) The 99214 E/M code (the level 4 code for established patients), "requires at least 2 of these 3 key components: A detailed history; A detailed examination; Medical decision making of moderate complexity." (2020 CPT Manual at 14.) It explains: "[u]sually, the presenting problem(s) are of moderate to high severity" and "[t]ypically, 25 minutes are spent face-to-face with the patient and/or family." (*Id.*)

The 2020 CPT Manual also explains that "[i]t should be recognized that the specific times expressed in the visit code descriptors are averages and, therefore, represent a range of times that may be higher or lower depending on actual clinical circumstances." (2020 CPT Manual at 8.) Quindoza testified that the time "represents the approximate time that it should take for a practitioner to provide the care associated with that code." (Tr. I-97.) He also testified that the time was not a requirement, and that if a provider was able to conduct the requisite exam, history, and decision making in five minutes, the visit could qualify as a level 4 visit. (Tr. I-199.) However, he also expressed skepticism that a provider could conduct the requisite history and exam in five

minutes. (Tr. I-200–01, Tr. I-209.)

2. COVID-19-Specific Rules and Guidance

During the COVID-19 pandemic, guidance was published regarding E/M coding. Witnesses testified that there was uncertainty regarding coding during this time. (*See, e.g.*, Tr. IX-19 (Miscoe testifying that "COVID was something that was unprecedented, that we'd never seen before in health care, even from a coding perspective . . . and the system wasn't prepared for it. Rules were coming out rampantly throughout 2020 and 2021"); Tr. III-97 (Raymond[6] testifying that, during the pandemic, "we were in a rapidly changing regulatory environment").)

CMS published an Interim Final Rule on April 6, 2020, which applied retroactively to March 1, 2020. That rule encouraged the use of telehealth and explained that "changes to Medicare payment rules will confer on practitioners and other healthcare providers the broadest flexibility to use remote communications technology[.]" (April 6, 2020 Interim Final Rule, Def. Ex. 218.) It further explained that:

> We are revising our policy to specify that the office/outpatient *E/M level selection for these services when furnished via telehealth can be based on MDM [medical decision making] or time, with time defined as all of the time associated with the E/M on the day of the encounter; and to remove any requirements regarding documentation of history and/or physical exam in the medical record.* This policy is similar to the policy that will apply to all office/outpatient E/Ms beginning in 2021 . . . It remains our expectation that practitioners will document E/M visits as necessary to ensure quality and continuity of care. To reduce the potential for confusion, we are maintaining the current definition of MDM.

(*Id.* (emphasis added).) Quindoza—the Government's coding expert—testified that he was unaware of this changed guidance. (Tr. II-22, Quindoza; *see also* Tr. I-220 (Quindoza testifying that he "forgot" about this guidance).) Miscoe explained that the Novitas worksheet was still used

[6] Cathy Raymond is a medical biller and certified medical coder who worked at Drs ERgent Care ("DEC") from January 2017 until October 2020.

to score a visit for purposes of medical decision making, but not for history and examination, as this rule advised that those components "no longer mattered." (Tr. VIII-185, Miscoe.)

May 6, 2020 guidance from the AMA provided that the full spectrum of E/M codes was available to providers to be billed for COVID-19 testing (i.e., levels 1 through 5 were available) for in-office and telehealth visits. (Gov't Ex. 919.) It also provided that, for "swab collection" visits, the 99211 code could be used. (*Id.*) Neither coding expert was asked about this document.

A May 8, 2020 Interim Final Rule explained that:

> Typically, collection of a specimen via nasal swab or other method during the provision of a service might be reported as part of (bundled with) an office/outpatient E/M visit (CPT codes 99201–99205, 99211–99215). In visits where a patient has face-to-face interaction with a billing professional with whom they have an established relationship, these services are generally reported with a level 2 through a level 5 visit (CPT codes 99212–99215). In cases where the specimen is collected during a visit where the face-to-face interaction only involves clinical staff of the billing professional with whom the patient has an established relationship, these services are generally reported using CPT code 99211 . . . .
>
> In considering possible codes for this purpose, we believe that CPT code 99211 for a level 1 E/M visit, appropriately describes the required clinical staff and patient interaction. However, billing for CPT code 99211 is currently limited to patients with whom the billing practitioner has an established relationship. As discussed above, CPT code 99211 typically does not involve interaction with physician or other qualified health care professional and the usual presenting problem(s) are minimal. Thus, this CPT code typically is reported by a physician or practitioner when the patient only sees clinical office staff for services like acquiring a routine specimen sample . . . . Therefore, for the duration of the PHE [Public Health Emergency], we will recognize physician and NPP [non-physician provider] use of CPT code 99211 for all patients, not just patients with whom they have an established relationship, to bill for a COVID-19 symptom and exposure assessment and specimen collection provided by clinical staff incident to their services.
>
> For the duration of the COVID-19 PHE, we are therefore finalizing on an interim basis that when the services described by CPT code 99211 for a level 1 E/M visit are furnished for the purpose of a COVID-19 assessment and specimen collection, the code can be billed for both new and established patients. We believe this policy will support expanded access to COVID-19 testing, and provide appropriate payment for COVID-19 testing-related services furnished by physician and other practitioners. This policy will allow physicians and practitioners to bill for services

> provided by clinical staff to assess symptoms and take specimens for COVID-19 laboratory testing for all patients, not just established patients.

(May 8, 2020 Interim Final Rule, Def. Ex. 219.) Miscoe testified that generally Medicare does not pay for "specimen collection and handling" and that this rule permitted the use of 99211 for collecting a sample, but that this code did not apply if a provider was involved in the patient encounter. (Tr. IX-88–89.) Miscoe testified that the guidance was that "if you weren't doing an evaluation and ancillary staff were simply obtaining a sample, then the work involved in that was to be billed as a level 1. But when an evaluation occurs, then you score the evaluation based upon, in 2021, medical decision making or time." (Tr. IX-15.) "Ancillary staff" included "anybody other than a licensed provider, such as a qualified health care practitioner or a physician." (*Id.*) Quindoza did not testify about this guidance.

May 22, 2020 guidance reiterates some of the earlier guidance, explaining that "the office/outpatient E/M services when furnished via telehealth can be based on medical decision making (MDM) or time, with time defined as all of the time associated with the E/M on the day of the encounter" and that "the typical times for purposes of level selection for an office/outpatient E/M are the times listed in the CPT code descriptor." (Def. Ex. 214 at 4.) It goes on to explain that "[p]hysicians and NPPs [non-physician providers] must use CPT code 99211 to bill for a COVID-19 symptom and exposure assessment and specimen collection provided by clinical staff (such as pharmacists) incident to the physician's or NPP's services." (*Id.* at 7.) Quindoza was not aware of this guidance prior to trial. (Tr. II-32 ("Q. All right. And until I showed you this today, had you ever seen it? A. No").)

On July 20, 2020, CMS and the Centers for Disease Control and Prevention ("CDC") announced in a press release that "payment is available to physicians and health care providers to counsel patients, at the time of [COVID-19] testing, about the importance of self-isolation after

they are tested and prior to the onset of symptoms." (Def. Ex. 233.) The press release further notes that "CMS will use existing [E/M] payment codes to reimburse providers who are eligible to bill CMS for counseling services no matter where a test is administered, including doctor's offices, urgent care clinics, hospitals and community drive-thru or pharmacy testing sites." (*Id.*) Quindoza testified that he was not aware of this press release prior to trial. (Tr. II-45 ("Q. . . . So do you recall this press release? A. No. I did not see it. Q. You did not see it? A. No, sir.").)

On September 2, 2020, CMS issued an additional Interim Final Rule. (Sept. 2, 2020 Interim Final Rule, Def. Ex. 220.) It provided that "CMS and CDC are also taking steps to ensure that physicians and other practitioners who counsel patients on COVID-19 testing are paid for these services. On July 30, 2020, CMS and CDC announced that payment is available to practitioners and suppliers to counsel patients, at the time of COVID-19 testing, about the importance of self-isolation after they are tested and prior to the onset of symptoms." (*Id.* at 20.) Quindoza testified that he did not recall ever reading this rule. (Tr. II-58 ("Q. And you don't recall ever reading this part of the interim final rule? A. No, sir, I did not.").)

In addition to including a CPT code when submitting claims to insurers, providers must include a diagnosis code, called the ICD-10-CM code. (Tr. I-106–07, Quindoza.) The 2021 ICD-10-CM Official Guidelines for Coding and Reporting indicated that: "During the COVID-19 pandemic, a screening code is generally not appropriate. Do not assign code Z11.52, Encounter for screening for COVID-19. For encounters for COVID-19 testing, including preoperative testing, code as exposure to COVID-19[.]" (Def. Ex. 221.) Miscoe testified that "with respect to COVID specifically, the guidance was that every patient was to be presumed to have had contact with and/or exposure to COVID, and that's the way the diagnosis coding, those instructions were."

(Tr. VIII-173; *see also* Tr. II-84 (Quindoza agreeing that the screening code should not be assigned because there was a pandemic).)

3. 2021 CPT Manual

The CPT code descriptions for E/M services changed in January 2021. And, as discussed in greater detail below, the five encounters that drew charges in the Indictment occurred in 2021.

Rather than use the three-factor model (i.e., history, examination, and medical decision making), the 2021 CPT Manual explained that providers were to "use medical decision making (MDM) ***or*** time as the basis for selecting a code level." (2021 CPT Manual at 5, Def. Ex. 4 (emphasis in original).) Miscoe explained that there was no required minimum time if the coding level was based on medical decision making. (Tr. VIII-188.) Further, the 2021 CPT Manual removed reference to "typical" times in the code descriptions.

The 2021 CPT Manual further explained that "the extent of history and physical examination is not an element in selection of the level of office or other outpatient codes." (2021 CPT Manual at 12.) Miscoe explained that the history and examination, in 2021, "has no relevance to scoring" and "[i]t's just not part of the analysis." (Tr. VIII-191.) Courtney Sinagra—a CareFirst auditor—did not agree that the only relevant factor is medical decision making, despite the language in the CPT Manual, but her testimony on this point is not clear. (Tr. V-142 (Q. And if the provider codes on medical decision making, then time is not relevant to selecting the level, is it? Correct? A. Not necessarily. But, yes, medical decision making in that instance would be the driver for that code. Q. Isn't it the only factor? It's one or the other. Isn't that what the manual says? A. No, it's not the only factor. The exam has to support the type of service that is rendered as well, and so does the complexity.").) The 2021 CPT Manual explained that:

> Office or other outpatient services include a medically appropriate history and/or physical examination, when performed. The nature and extent of the history and/or

> physical examination are determined by the [provider]. The care team may collect information and the patient or caregiver may supply the information directly (eg, by electronic health record [EHR] portal or questionnaire) that is reviewed by the reporting physician or other qualified health care professional.

(2021 CPT Manual at 12.)[7]

In the 2021 CPT Manual, to qualify as a level 4 visit when coding based on medical decision making (as opposed to time), the visit was required to include moderate level medical decision making and "medically appropriate history and/or examination." (2021 CPT Manual at 19.) Miscoe testified that "the requirement is for a medically appropriate history and/or physical examination when performed, which suggests, if it's performed, it needs to be medically appropriate. What that means, I don't know, and more importantly, I don't care because it's not part of the scoring elements." (Tr. VIII-191; *see also* Tr. II-10 (Quindoza agreeing that, in 2021, the was no requirement for a level 4 visit to have a "comprehensive history or a comprehensive examination").) If a visit was instead coded based on time, to qualify as a level 4 visit, a provider was required to spend 45–59 minutes of total time on the date of the encounter for a 99204 visit, and 30–39 minutes for a 99214 visit. (2021 CPT Manual at 19.)

The 2021 CPT Manual explains that medical decision making "is defined by three elements": "[t]he number and complexity of problem(s) that are addressed during the encounter"; "[t]he amount and/or complexity of the data to be reviewed and analyzed"; and "[t]he risk of complications and/or morbidity or mortality of patient management decisions[.]" (2021 CPT Manual at 14.) The 2021 CPT Manual also includes a table, which is a "guide to assist in selecting the level of MDM for reporting an office or other outpatient E/M services code." (*Id.* at 15.) The

[7] Miscoe also explained that, to the extent time was used to drive the code selection, the time spent included "both face-to-face and non-face-to-face time," which included "anything from reviewing the history or reviewing patient records prior to an encounter, doing any history, examination, and so forth, counseling . . . [and] even completing the medical record documentation[.]" (Tr. VIII-189.) He testified that this was a "big difference" from the 2020 CPT Manual, where the time spent had to be face-to-face with the patient. (*Id.*)

Manual explains that, "[t]o qualify for a particular level of MDM, two of the three elements for that level of MDM must be met or exceeded." (*Id.*) The table is provided below:

Evaluation and Management (E/M) Services Guidelines CPT 2021

►Table 2: Levels of Medical Decision Making (MDM)◄

		Elements of Medical Decision Making		
►Code	**Level of MDM** (Based on 2 out of 3 Elements of MDM)	**Number and Complexity of Problems Addressed at the Encounter**	**Amount and/or Complexity of Data to be Reviewed and Analyzed** ***Each unique test, order, or document contributes to the combination of 2 or combination of 3 in Category 1 below.***	**Risk of Complications and/or Morbidity or Mortality of Patient Management**
99211	N/A	N/A	N/A	N/A
99202 **99212**	**Straightforward**	**Minimal** • **1** self-limited or minor problem	**Minimal or none**	**Minimal risk of morbidity from additional diagnostic testing or treatment**
99203 **99213**	**Low**	**Low** • **2** or more self-limited or minor problems; **or** • **1** stable, chronic illness; **or** • **1** acute, uncomplicated illness or injury	**Limited** *(Must meet the requirements of at least 1 of the 2 categories)* **Category 1: Tests and documents** • **Any combination of 2 from the following:** ▪ Review of prior external note(s) from each unique source*; ▪ Review of the result(s) of each unique test*; ▪ Ordering of each unique test* **or** **Category 2: Assessment requiring an independent historian(s)** *(For the categories of independent interpretation of tests and discussion of management or test interpretation, see moderate or high)*	**Low risk of morbidity from additional diagnostic testing or treatment**
99204 **99214**	**Moderate**	**Moderate** • **1** or more chronic illnesses with exacerbation, progression, or side effects of treatment; **or** • **2** or more stable, chronic illnesses; **or** • **1** undiagnosed new problem with uncertain prognosis; **or** • **1** acute illness with systemic symptoms; **or** • **1** acute, complicated injury	**Moderate** *(Must meet the requirements of at least 1 out of 3 categories)* **Category 1: Tests, documents, or independent historian(s)** • **Any combination of 3 from the following:** ▪ Review of prior external note(s) from each unique source*; ▪ Review of the result(s) of each unique test*; ▪ Ordering of each unique test*; ▪ Assessment requiring an independent historian(s) **or** **Category 2: Independent interpretation of tests** • Independent interpretation of a test performed by another physician/other qualified health care professional (not separately reported); **or** **Category 3: Discussion of management or test interpretation** • Discussion of management or test interpretation with external physician/other qualified health care professional/appropriate source (not separately reported)	**Moderate risk of morbidity from additional diagnostic testing or treatment** *Examples only:* • Prescription drug management • Decision regarding minor surgery with identified patient or procedure risk factors • Decision regarding elective major surgery without identified patient or procedure risk factors • Diagnosis or treatment significantly limited by social determinants of health

Code	Level of MDM (Based on 2 out of 3 Elements of MDM)	Elements of Medical Decision Making: Number and Complexity of Problems Addressed at the Encounter	Amount and/or Complexity of Data to be Reviewed and Analyzed *Each unique test, order, or document contributes to the combination of 2 or combination of 3 in Category 1 below.*	Risk of Complications and/or Morbidity or Mortality of Patient Management
99205 99215	High	**High** • **1** or more chronic illnesses with severe exacerbation, progression, or side effects of treatment; **or** • **1** acute or chronic illness or injury that poses a threat to life or bodily function	**Extensive** *(Must meet the requirements of at least 2 out of 3 categories)* **Category 1: Tests, documents, or independent historian(s)** • **Any combination of 3 from the following:** ▪ Review of prior external note(s) from each unique source*; ▪ Review of the result(s) of each unique test*; ▪ Ordering of each unique test*; ▪ Assessment requiring an independent historian(s) **or** **Category 2: Independent interpretation of tests** • Independent interpretation of a test performed by another physician/other qualified health care professional (not separately reported); **or** **Category 3: Discussion of management or test interpretation** • Discussion of management or test interpretation with external physician/other qualified health care professional/appropriate source (not separately reported)	**High risk of morbidity from additional diagnostic testing or treatment** *Examples only:* • Drug therapy requiring intensive monitoring for toxicity • Decision regarding elective major surgery with identified patient or procedure risk factors • Decision regarding emergency major surgery • Decision regarding hospitalization • Decision not to resuscitate or to de-escalate care because of poor prognosis◀

(*Id.* at 16–17.) As reflected in the table above, a "moderate" level visit (i.e., a 99204/99214 visit) occurs if a patient presents with "1 undiagnosed new problem with uncertain prognosis" and if the visit includes "[a]ny combination of 3 from the following: Review of prior external note(s) from each unique source; Review of the result(s) of each unique test; Ordering of each unique test; Assessment requiring an independent historian(s)[.]" (*Id.* at 16.) The Manual specifies that "[e]ach unique test . . . is counted to meet [the] threshold number." (*Id.* at 14.) Thus, ordering two tests and reviewing the results of one of those tests can qualify under this rubric. The CPT Manual defines "undiagnosed new problem with uncertain prognosis" as "[a] problem in the differential diagnosis that represents a condition likely to result in a high risk of morbidity without treatment. An example may be a lump in the breast." (*Id.* at 13.) "Morbidity" is defined as: "[a] state of illness or functional impairment that is expected to be of substantial duration during which function

is limited, quality of life is impaired, or there is organ damage that may not be transient despite treatment." (*Id.* at 14.)

B. Provider Encounters at DEC

The Defendant opened Drs ERgent Care ("DEC") in Gambrills, Maryland in 2016 and was an owner (along with Sid Saab, Gary Day, and Jeff May); the Defendant was also the medical director of DEC. (Tr. IX-119–20, Elfenbein.) In early 2020, DEC merged with Centennial Medical Group—which was headed by Connor Ferguson—and DEC became FirstCall Medical Center.[8] (Tr. IX-127–129, Elfenbein.) In addition to the Gambrills urgent care location, DEC opened COVID-19 testing sites at the Earleigh Heights Volunteer Fire Department and the Odenton Volunteer Fire Department, as well as infusion centers. (Tr. IX-173, Elfenbein.)

After the onset of the COVID-19 pandemic, "there was a near overnight demand for COVID testing, so [DEC] pivoted away from many of [its] traditional urgent care services" to provide COVID-19 testing. (Tr. III-82, Raymond.) This was accompanied by a significant increase in the number of patients. (*Id.*)

1. COVID Testing Process

The COVID-19 testing process at DEC locations evolved during 2020–2022. However, the evidence at trial generally established the following process: patients completed registration paperwork; were seen by a medical assistant ("MA"), who took the patients' vitals and samples for a COVID-19 rapid test and a PCR test; the patient saw a provider either in person (such as at the Gambrills location) or remotely via a monitor (such as at the Earleigh Heights location);[9] and

[8] The Court will refer to the entity at issue as "DEC" throughout this Memorandum.

[9] The five charged counts involve patient encounters that occurred remotely at the Earleigh Heights location.

the patient received positive rapid test results by phone and all PCR results in a follow up e-visit. Each of these steps is described in more detail below.

As an initial matter, witnesses generally testified that conducting an E/M visit in addition to providing COVID-19 testing was medically appropriate, and no witness testified otherwise. (*See, e.g.,* Tr. VIII-74–76 (Hill[10] testifying that a provider should do some degree of history and examination before providing a test); Tr. VIII-102 (Hill testifying that the care provided to each of the patients in the charged counts was "reasonable, necessary, and prudent"); Tr. II-61 (Quindoza agreeing that CMS and the CDC "wanted to have a [provider] see a patient and have an evaluation and management visit, have an office visit, on the same day as a test.").)

At each patient encounter, the patients completed registration paperwork, which included questions regarding symptoms, medications, history, demographic information, reasons for being tested, and conditions that might put a patient at particular risk if they were to contract COVID-19. (Tr. IV-136, Needle;[11] Tr. V-193–194, Tr. VI-12, Wrona;[12] Tr. VIII-12–13, Carroll;[13] Tr. IX-99, Elfenbein.) The MAs took the patients' vitals—including pulse, blood oxygen level, and temperature—and swabbed patients for a rapid test and a PCR test. (Tr. IV-136, Needle; VI-18, Wrona; Tr. VIII-52, Davis;[14] Tr. IX-98–99, Silva.[15])

[10] Hugh Hill, a Defense expert, is a doctor who was qualified as "an expert in the field of emergency medicine, and in particular the treatment of patients who have been exposed or have symptoms of COVID-19." (Tr. VIII-72.)

[11] Deborah Needle is a nurse practitioner who worked at DEC from 2019 to November or December 2020.

[12] Kathleen Wrona is a physician assistant who worked at DEC from January 2021 to September 2021.

[13] Steven Carroll is a nurse practitioner who was hired by DEC in September 2020 and who still works at DEC.

[14] Sharron Davis is a medical assistant who was hired by DEC at the end of 2021 and who still works at DEC.

[15] Suzanna Silva is a physician assistant who was hired by DEC in September 2021 and who still works at DEC.

Then, patients saw a provider. At the Gambrills location, the provider saw the patient in-person, while at Earleigh Heights, the provider saw the patient remotely, via a monitor. Hill testified that, if the visit is virtual, a provider is "limited in what [they] can do, but [they] can do some exam." (Tr. VIII-111.) The provider visits were brief. For instance, the patients that are the subject of the charged counts testified that their encounters lasted a few minutes each. (*See, e.g.*, Tr. IV-108 (S.T. testifying that the appointment for W.R. lasted "less than five minutes"); Tr. IV-101–02 (S.T. testifying that the encounter with the provider lasted "[f]ive, ten minutes" with the provider, which included seeing her and her three children); Tr. V-6 (J.J. testifying that the encounter with the provider lasted about two minutes).)

The providers testified that they asked the patients questions regarding any symptoms or other issues and made medical judgments regarding the patients they saw; they also testified that they conducted physical exams for in-person visits and visual exams for virtual visits. (*See, e.g.*, Tr. IV-190–191 (Needle agreeing that she made medical judgments regarding the patients, including whether a patient was symptomatic or asymptomatic; the appropriate care; whether a patient is immunocompromised; what kind of test to perform; and other items); Tr. VI-19–21 (Wrona testifying that she generally did not do an exam of the virtual patients, but that she would look at the appearance and demeanor of each patient, and that she would use her medical judgment during the visits); Tr. VIII-12–15 (Carroll testifying that he performed a physical exam on patients that presented for in-person visits and visual exams on virtual visit patients, that he discussed symptoms and performed a review of systems, and that he asked questions and provided recommendations); Tr. VIII-57–60 (Davis testifying that the providers did a "thorough check over" because it was an urgent care center, not just a "COVID run-through site" and that, for virtual visits, "the only difference is, they're not doing it hands-on, but they're speaking"); Tr. IX-99–101

(Silva testifying that she conducted physical exams for in-person visits and visual exams for virtual visits, including assessing whether patients were breathing well).)

Patients generally received rapid tests results on the same day as the appointment. (Tr. V-195, Wrona.) PCR tests were available after. Patients with positive rapid tests were called, and all patients were called with PCR results, whether positive or negative. (Tr. VIII-29–31, Carroll.) The PCR test result calls were also billed using E/M codes. (Tr. IV-12, Raymond.)

2. DEC Testing Volumes

Providers sometimes saw a very large number of patients in a single day. For instance, Carroll testified that he could see 150 patients on a busy day. (Tr. VIII-15.) In a November 14, 2020 email, the Defendant states that "[o]ur volumes continue to explode" and that two providers "yesterday [saw] over 350 people." (Gov't Ex. 638; *see also* Gov't Ex. 643 (December 11, 2020 email from the Defendant explaining that "[Earleigh Heights] opened this week and we are already seeing over 150, so we need to provide more and better staffing. I came in today to help [] after doing a 24 ER shift-we saw almost 170 today (day 5) without doing any advertising.").) In a January 18, 2021 email, a provider emails the Defendant that "I feel there is the constant pressure of moving a herd of cattle through a pass at 60 heads *per minute*." (Gov't Ex. 658 (emphasis in original).)

The Defendant also sent emails during this period directing providers to see patients quickly. For instance, in a December 25, 2020 email, he states: "Remember this is virtual and [the patient] is there for one reason only-to be tested. Goal is to get them seen and out quickly (we want them in and out of the tent in under 5 minutes total). We are not there to solve complex medical issues, etc… Just to test them. ANY issues outside of that, refer them to Gambrills, their PMD, or the ER (if they look bad)." (Gov't Ex. 647; *see also* Gov't Ex 646 (December 24, 2020 email in which the Defendant states "1) Patients just want to get tested and go home[.] Speed here

is key[.] 2) the patients are all here for one reason…. Simple and straightforward-to get tested.").) In addition, providers were given incentives for seeing large numbers of patients, and received extra time to complete patient charts if they saw a certain number of patients. (*See, e.g.*, Gov't Exs. 644, 645.)

3. Templates and Documentation

The evidence presented at trial makes clear that there were problems with client documentation and billing. DEC began using a system called NextGen to document patient visits in early 2020. The transition to NextGen was challenging, and it was exacerbated by the pandemic. At the beginning of the pandemic, DEC developed a backlog of nearly 20,000 claims despite "working diligently" to resolve outstanding claims. (Tr. III-30:2–4, Turner.)

Templates are a method of documenting client encounters and are commonly used in the medical profession. (Tr. IV-30–31, Raymond; Tr. VIII-95, Hill; Tr. VIII-19 (Carroll testifying that templates are commonly used and that they are helpful because it could take "upwards of two to three hours" to document a client encounter without a template).) Given the issues with billing and chart backlogs, templates could be helpful for speeding up the process of documenting client encounters. (Tr. IV-29–30, Raymond; *but see* Tr. IV-94 (Raymond testifying that she disliked templates, because it could result in incorrect patient information if there were copy-paste errors).)

The Defendant created templates (sometimes referred to as "T-Sheets") for patient encounters. (Tr. V-195, Wrona.) There were different templates for different locations and a "T-Sheet" for Earleigh Heights. (Tr. VI-27, 38, Wrona.) In a July 2020 email, Raymond and the Defendant provided instructions regarding how to complete the documents. (Gov't Ex. 617.) One provider responded that it "works great" and is "so fast and easy" and that the "entire patient

encounter and chart took 20 seconds." (*Id.*) The Defendant responded that everyone should "use the T-sheets moving forward for ease and speed." (*Id.*)

The providers at DEC generally used the templates to document their patient encounters, but their testimony regarding their use of templates varied. For instance, Needle testified that the templates came from management, that providers were required to use them, and that some portions of the templates were locked. (Tr. IV-137–38.) Needle did not like that they were locked because her "exam is very individualized" and "[e]very patient is different." (*Id.*) Carroll, on the other hand, testified that he made changes to the templates and that he made his own templates. (Tr. VIII-20, 31–32 (Carroll also testifying that he recalled that the templates provided by the Defendant were "sometimes . . . a bit bloated.").) Silva also testified that she made templates for herself for COVID-19 patients, and that the Defendant never told her not to make her own templates. (Tr. IX-103.)

Providers uniformly testified that they endeavored to document patient records accurately, and that they were not instructed to do otherwise. (*See* Tr. VI-29 (Wrona agreeing that her goal was to make the T-Sheets as accurate as possible and that she was not advised to put inaccurate information in them); Tr. VIII-18–19 (Carroll testifying that he sometimes made mistakes in documenting patient encounters, but that no one ever told him to sign and bill charts that contained incorrect information).) There were times that the patient documentation was inaccurate. For instance, in the "physical exam" section of a patient record, Wrona testified that there were certain items in the record that were inaccurate. (*See* Tr. V-204 ("Q. Did do you the physical exam that's depicted here in this record? A. No, I did not do all of it. Some of it would be like, yes, they're awake, alert, and that sort of thing. But when it says under ENT, i.e., 'the pharynx is without exudates,' I would not have seen that."); *see also* Tr. VI-30 (Wrona testifying that they had "so

many patients that [they] couldn't . . . document everything for every single patient"); Tr. IX-105 (Silva testifying that there were occasional mistakes in patient documentation).)

The templates included form language that was the same across multiple patients. For example, the template indicated "Patient is here for a COVID exposure" regardless of the reason for which the patient was being tested. In addition, the Government presented evidence that identical language was used for multiple patients. (*See, e.g.*, Excerpts from Gov't Ex. 402; Gov't Ex. 403.)

C. Coding at DEC

The Defendant instructed the providers to code the COVID-19 testing visits as level 4 for asymptomatic patients and level 5 for symptomatic patients. Nearly every patient presenting to DEC for a COVID test—regardless of the reason for which that patient wanted a COVID test—was billed as a level 4 office visit. (*See, e.g.*, Tr. II-164 (Turner testifying that in April 2021, at the Gambrills location, "[n]early 96 percent [of E/M visits were billed] at a level 4, and then 2.8 percent at a level 5"); *see also* Gov't Ex. 137.) DEC primarily billed the visits using the z20.822 and z20.828 diagnosis codes. (Tr. I-120-21, Quindoza; Gov't Ex. 108; Gov't Ex. 109.)

1. Decisions and Communications Regarding Coding and Patient Encounters

The Defendant testified at trial. He explained that in March 2020, he, Saab, and Ferguson agreed that level 4 was appropriate for asymptomatic patients and level 5 was appropriate for symptomatic patients. (Tr. X-66; *see also* Tr. X-156–57 (Elfenbein testifying that they discussed the coding levels and "identified that we believed that was appropriate. We cc'd and we brought in Ms. Raymond, and she gave her opinion, and she said that she questioned a level 5, but level 4 did not seem to pose a problem to her. And throughout the entirety of pandemic when she was employed with us, she never once said to me or anybody else, 'We don't believe this is

appropriate.'").) He testified that no one consulted a CPT Manual at the time, and that, while that was not ideal, there were "a million things going on"; that "[w]e did the best we could at the time"; and that, when he did have time, he reviewed the CPT Manual. (Tr. X-157–58.) He explained that, "based on my understanding of the codes at the time and the E/M levels at the time, it made sense. It was a new virus. It was potentially deadly. The world was shut down. It's unprecedented." (Tr. X-67.)

In a March 2020 email chain between Raymond, the Defendant, Ferguson, and Saab, Raymond said:

> I checked the reimbursement for the 99421 series and the lower end is at $16, a 99201 is paying about $47 per Medicare FFS, and would remain the same under payment parity laws. We'd come out ahead by doing lower-level office visit codes and not risk as many denials . . . .
>
> The Defendant responds: There has to be a way to bill higher level on these. I heard they were waiving the restrictions during this to bill 'normal' visits using telehealth. Sid, can you w[eigh] in on this. We cannot afford to only reimburse at 16$/visit…. They should all be level 3 or 4 by definition-possible [covid] exposure…. We need to figure this out ASAP."
>
> Raymond responds: We'd only be running into the $16/visit if I billed it as a 99421 series, which is online evaluation and management and is restricted to established patients. If it is billed as a 99201 (which is a normal visit code), POS 02 and modified 95 in place, that's still low but is about $50. For an established patient it would be 99212 at lowest and that pays at $48. What's dragging it down is the lack of exam. I had proposed the time based rules as a way around it since the second you introduce time I have to disregard the 3 key elements and go based solely on time.
>
> The Defendant responds: . . . . This is Connor territory . . . . Issue is we want to bill for the visit but we ARE NOT DOING AN EXAM…. We don't want E/M to be level 1… Should be 3-4. Thoughts?

(Def. Ex. 13.) Raymond responds, providing a description of a sample patient exam that could be done virtually and stating that it is "a solid 3 under the 1995 system" and that she "hate[s] being inconsistent with standards but in this case for NextGen it levels in the 1997 system" and that she

"will most likely have to level into the 1995 system due to the limitations of the system." (*Id.*) The Defendant responds "I don't understand this and will defer to Connor on this one." (*Id.*)[16]

In a March 2020 email chain, Ferguson says: "[f]or patients seen on site for [upper respiratory infection], whether through a video visit in the car or Face to Face in an exam room, they will be a level 4 for our Flu/Strep/RSV protocol, it will move to a level 5 if we administer a Sars2/Covid-19 screening . . ." (Gov't Ex. 602.) Raymond responds "Template has been put in. . . . For drive-up and face to face, that is okay with me." (*Id.*) Raymond later says:

> The second thing is I'm going to need solid MDM. As I have to lean heavily on both history and MDM they need to be solid . . . . All I need is what are we going to do with this patient. I honestly don't think there's going to be enough clinically to justify the level 5 that Connor's saying. There's no cure or treatment outside of supportive for this thing, and unless the patient's in respiratory distress I don't know I can make a case for threat to life or limb stick. If you say there is I'll take your word for it, but I can't exceed what the documentation supports. I know CMS has said they won't look too closely but that was just in 1 area, new vs established. That's not carte blanche for over coding.

(*Id.*) During her testimony, when asked whether it was "okay with [her] to use the [] level 4 and 5" she stated: "If I had the documentation to support it in the history and the exam. More often than not, I didn't." (Tr. IV-45.)

The emails throughout the spring and summer of 2020 reflect the Defendant providing instructions to his staff to code asymptomatic patients as a level 4 and symptomatic patients as a level 5. The emails also reflect him pressing providers to complete patient documentation. For example, in an April 25, 2020 email to various DEC employees, the Defendant explains:

> 1) Asymptomatic people we are testing…. You need to put something in the note as to why we are testing. Either they have a cold/some sort of symptom, they live

[16] The Defendant testified that he understood that the patient visits should be a level 3 or 4 based on "[his] understanding and [his] discussions internally" with Raymond, Saab, and Ferguson. (Tr. X-76.) He explained that his comment related to the lack of exam in the traditional sense, given that certain of these encounters were going to be virtual. (Tr. X-78.)

> with a high risk person, they think they were possibly exposed, they work in a nursing home, etc… SOMETHING…. That need to be documented. We just need a reason to test to be documented.
>
> . . . .
>
> 3) E+M…. If we are testing for Covid-19 presumably they meet criteria for certainly level 4, likely level 5 (PPE needed, potentially fatal virus exposure/rule out, etc..). Please keep this in mind. The level 5 designation applies to symptomatic people-not asymptomatic people-they would likely be level 4.

(Gov't Ex. 605; *see also, e.g.*, Gov't Ex. 606 (May 2020 email from the Defendant to various providers and others that "Charts NEED to be completed within 24 hours of [date of service]-this is non negotiable" and "[r]emember, most of the Covid patients should be level 4 and if they are symptomatic, they should really be level 5- deadly virus, PPE use, etc.[] Please remember to document these things to help support your MDM and why you chose the E&M level you did. ANY questions, let me know."); Gov't Exs. 607, 609, 614.)

The Defendant also sent emails describing coding in greater detail. For instance, in a September 11, 2020 email to providers and others, the Defendant wrote:

> I just learned that not everyone understands E/M coding and such so I want to explain it and give a brief overview. Please read this and pay attention to this. This is REALLY important, so if you have any questions, please let me know.
>
> First off, E/M code stands for Evaluation and Management. It is a five-level coding system designed and implemented by CMS (Medicare) to express the complexity of the visit. [I]t is labeled as such: 99201-99205 and 99211-99215 and is universally used by all insurances to bill for visits.
>
> The ones with the 01-05 are for NEW patients and the 11-15 are for ESTABLISHED patients (seen by the practice within the past three years). The higher the last digit (1-5)[,] the higher is the complexity of the visit and the more charged/paid. The complexity of the visit is determined by many factors: including complaint, abnormal vitals, medical hx, medical decision making, NUMBER of systems you do under ROS, NUMBER of systems you examine under physical, potential for "danger", etc.

(Gov't Ex. 626.) The email then goes on to describe, *inter alia*, the physical exam. (*Id.*) The Defendant states that providers should "be sure to actually make note of the things you are

documenting and DO THE THINGS you are documenting." (*Id.*) He also states that "[t]he coding level really is determined primarily by 3 factors: history, evaluation and complexity of medical decision making. Documentation is key to this. We need proper documentation to be able to substantiate the level coded for." (*Id.*) He also notes that "[t]he Medical Decision Making is where you document: what you did, why you did it and anything abnormal." (*Id.*) He says that "[t]he importance of this is that [this] is the 'bread and butter' of how we get paid. Each payor pays a set amount for the E/M depending on the level of complexity-i.e. a 99202 pays way less than a 99204. Right off the bat, an [] 'established' patient pays significantly less than a new one even for the same E/M level. This is where most practices-ours included-capture 80% or so of its revenue. So, hopefully you can see the importance." (*Id.*) Several other similar emails were introduced at trial.

2. Testimony Regarding Coding Levels

a. Government Expert

The Government presented one expert at trial. As noted above, Quindoza was qualified as an expert in Medicare; Medicare processes, rules, and regulations, including enrollment, participation, the processing of claims, coverage, and procedural and diagnostic coding. (Tr. I-62.) Quindoza—although qualified as an expert—was unfamiliar with coding guidance that had been issued during the course of the pandemic, as discussed above. For instance, he testified that he was not familiar with the rules that removed the examination and history requirements for virtual visits and acknowledged that he had not read the Interim Rules and guidance. He had to backtrack with respect to some of his testimony regarding the relevance of time. Moreover, Quindoza did not testify as to the appropriate coding levels for any of the COVID-19 testing encounters, did not illuminate any of the definitions in the CPT Manual, and did not testify

regarding the appropriate code for any of the charged counts. The Government does not cite to his testimony in its briefing other than to establish a minor technical point regarding DEC's ownership.

b. Defense Experts

Miscoe, who was qualified as an expert "in the fields of medical coding, evaluation and management coding, diagnostic coding, documentation of medical services and medical records" (Tr. VIII-133), testified about terms in the CPT Manuals and related guidance and regarding the five charged encounters, concluding that they were properly coded as level 4 visits because they each involved an "undiagnosed new problem with uncertain prognosis" and because the ordering of two tests and reviewing one test qualified to meet the thresholds in the medical decision making chart.

He testified that COVID-19 was an undiagnosed new problem with uncertain prognosis. He explained that because "[w]e have [an] undiagnosed new problem . . . then it's a question of whether we believe the prognosis for someone who potentially has COVID is well-defined, and I don't believe that it is." (Tr. VIII-179–80.) He explained that the other descriptors provided in the CPT Manual—self-limited or minor problem; stable, chronic illness; and acute, uncomplicated illness or injury—did not accurately describe a COVID-19 testing encounter. (*Id.*) He testified that "the idea that it's a self-limited or minor problem is somewhat absurd because otherwise, if it was, we wouldn't have had a Public Health Emergency over it." (*Id.*) He also testified that the "acute" and "chronic" descriptors could not apply to a COVID-19 testing patient, because "we don't even have a diagnosis yet" and therefore do not know how long the patient has had the condition. (*Id.*) Miscoe also testified that the reason for which the patient was being tested did not matter, because "there was a presumption that they had contact with or exposure" to COVID-19, given that providers were instructed to use the Z20.828 and Z20.822 diagnosis codes. (Tr.

VIII-173–174.) He also testified that when a provider is selecting a CPT code based on medical decision making, he is coding "the process versus the result." (Tr. VIII-200.)

He explained that ordering two tests—the rapid test and the PCR test—and reviewing the rapid test on the date of the encounter met the threshold required under the 2021 CPT Manual to qualify as a level 4 visit. (*See, e.g.*, Tr. VIII-197–98.)

As discussed in more detail below, Miscoe ultimately testified that the five charged encounters were appropriately coded as level 4 visits.[17]

Miscoe explained that it would not surprise him that the majority of visits at an urgent care center or a testing site would be billed at a level 4. (Tr. IX-8.) He also explained that it would not surprise him if there was common language in various medical charts, as that is "just the nature of electronic medical records." (Tr. IX-9 (Miscoe explaining that "when you're evaluating the same condition, templates are used based upon what the query is that's relevant to that condition, and in which case they're going to look the same.").)

Hill, an emergency room doctor who was qualified as "an expert in the field of emergency medicine, and in particular the treatment of patients who have been exposed [to] or have symptoms of COVID-19" did not testify regarding coding levels. He testified regarding the medical necessity and propriety of the patient visits. He also testified that he "doubted" that the DEC providers could see over 150 patients a day. (Tr. VIII-106.) He explained that he believed that this was "an

[17] Miscoe also concluded similarly with respect to 2020 visits, using the Novitas scoring matrix described above. (Def. Ex. 1.) Using that matrix, Miscoe scored patient records that were the subject of the CareFirst Audit (described in more detail below). (Tr. VIII-158–181.) That patient presented to DEC to be tested for COVID-19. Miscoe scored the various components: history (including history of present illness, review of systems, and past medical, family, and social history); examination; and medical decision making. (*Id.*) After walking through the chart and scoring each of these components, he explained that the patient visit qualified as a level 4, because the patient records supported a comprehensive history, a comprehensive examination, and moderate level decision making. (*Id.*)

Quindoza was not asked to conduct a similar analysis in his testimony, either with respect to the Novitas matrix or the 2021 medical decision making chart.

excessive burden" and that it seems "highly unlikely" and that 150 patients are "too many to have time for, even if you're working . . . a 24-hour shift." (*Id.*) He also testified that he has treated a patient in 20 seconds or less, but that he wouldn't want to and that he could not do "an entire history and physical" in one minute. (Tr. VIII-114–15.)

c. CareFirst Audit

CareFirst conducted two audits of DEC, which Sinagra supervised. (Tr. V-28–29, Sinagra.) For the first audit, CareFirst requested medical records for 30 patients. (Tr. V-30, Sinagra.) CareFirst requested the records four times before it received them, and when they received the records, they were incomplete. (Tr. V-30–31, Sinagra.) A fax coversheet dated March 19, 2021 from FirstCall Medical Center states: "I'm new at this position of gathering patient records. If anything is missing please do not hesitate to contact me. I do apologize for the time it took to gather this information." (Gov't Ex. 401.) Sinagra testified that it appeared that "[p]ages were omitted during the fax process or weren't printed in consecutive order." (Tr. V-32; Tr. V-96 (Sinagra estimating that 40 percent of the pages were missing).) Miscoe testified that it was not proper to conduct an audit based on incomplete records. (Tr. IX-16.)

The first audit was issued on April 28, 2021. (Gov't Ex. 501.) The audit identified the following issues: (1) "Medical Records Documentation Standards"; (2) "Improper Coding"; and (3) "Service Not Rendered." (*Id.*) Sinagra testified that the general finding of this first audit was that DEC was "not adhering to medical policy in the provider contract[.]" (Tr. V-35.) The auditor determined that the more appropriate code was level 3. (Tr. V-108–13, Sinagra.) Sinagra testified that she agreed that she did not know whether the records would have supported the level 4 claims DEC made. (Tr. V-127–28.)

The Defendant testified that he was not aware of this audit until the Government produced it in discovery in relation to the instant criminal case. (Tr. X-144.) The audit report provides that DEC may submit a reconsideration request, but DEC did not submit a reconsideration request. (Tr. V-34, Sinagra.)

The second audit was conducted after CareFirst "received a notification from CMS, Medicaid, outlining potential issues with coding and compliance to our Medicaid program." (Tr. V-35, Sinagra.) The second audit was issued on March 8, 2022. (Gov't Ex. 502.) The "purpose of th[e] audit was to determine if the services billed by the office of Drs. Ergent Care and Dr. Ron Elfenbein, were submitted utilizing CareFirst's established criteria (i.e. coding and/or supporting documentation)." (*Id.*) The issues identified in the audit included:

> ISSUE: CPT 99204 (Services prior to 2021) Office or other outpatient visit for the evaluation and management of a new patient, which requires three key components: A comprehensive history; A comprehensive examination; Medical decision making of moderate complexity. Typically, 45 minutes are spent face to face with the patient and/or family. (55 Claims)
>
> The medical records provided by your office did not document the following:
>
> > The documentation did not support a comprehensive history, a comprehensive examination or moderate complexity decision making. The documentation supported an expanded problem focused history, an expanded problem focused examination and a straightforward medical decision making; therefore 99202 is the appropriate code.
>
> ISSUE: CPT 99204 (Services after 2021) Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using time for code selection, 45–59 minutes of total time is spent on the date of the encounter. (13 Claims)
>
> The medical records provided by your office did not document the following:
>
> > The documentation did not support a medically appropriate history and/or examination and moderate level of medical decision making. Documentation did not specify the total time spent on the date of the encounter. The documentation supported a medically appropriate history and/or examination and straightforward medical decision making, 15–29 minutes of total spent on the date of the encounter; therefore 99202 is the appropriate code.

> CareFirst reviewed a total of 68 instances for which CPT 99204 was billed. The documentation did not support the billing of 68 instances. The total overpayment amount for the identified claims is $8,635.95.

(Gov't Ex. 502.) The audit report concluded similarly with respect to the established patient code (i.e., 99214) and with respect to the level 5 claims for an established patient (i.e., 99215). (*Id.*)

DEC submitted a reconsideration request through counsel. (Gov't Ex. 517.) In it, DEC explained that the patient records reviewed in the audit meet the requirements for level 4 and level 5 visits. (*Id.*) DEC argued that level 2 is not correct, as the visits did not involve self-limited or minor problems, that COVID-19 qualifies as an undiagnosed new problem with uncertain prognosis, and that, given the multiple lab results and data, level 4 or 5 would be appropriate. (*Id.*) The letter also noted that DEC apologizes for its failure to timely respond, as the audit did not reach the appropriate personnel. (*Id.*)

Sinagra testified that it would not be out of the ordinary to have a one-level difference between coding in audits and that it would "be fair to say that auditors don't necessarily make the same findings as to specific claims." (Tr. V-150.) Sinagra testified that COVID-19 "could be" an undiagnosed new problem with uncertain prognosis, or that it could be straightforward. (Tr. V-171–72.)

d. DEC Employees

Some former and current DEC employees testified that they were not comfortable with the level 4 billing, while others testified that they were comfortable with billing at that level.

Cathy Raymond testified that she believed that the COVID-19 testing encounters should have been billed at a level 3. (Tr. IV-49.) Raymond testified that she expressed concerns about the coding to the Defendant multiple times. (Tr. III-84.) She explained that, while she did not raise concerns about level 4 coding in particular, she raised concerns about over-billing in general. (Tr. IV-49.) She explained that she was concerned about "over coding of office visits" and that

she told the Defendant that "what [she was] seeing document-wise is not supporting" the "high-level office visits" and that she "need[s] to have a complete patient history entered, and it was not entered" and that "in order for us to be billing those high-level office visits, I need to have a complete history entered, and it was not entered." (Tr. IV-6–7.) She also testified that she had "considered multiple different code options to see which one actually accurately described the service and which one would be compliant because we were in a rapidly changing regulatory environment." (Tr. III-97, Raymond.) She explained that "the insurance regulations were very unclear as to coverage." (*Id.*)

Deborah Needle testified that she believed that the more appropriate code for an asymptomatic patient was a level 3 and that "[h]istorically, that was [her] feeling, but [she] had never lived through a pandemic before." (Tr. IV-206–07.) Needle also testified that, prior to working at DEC, she did not have coding experience. (Tr. IV-134.) She explained that she "told [the Defendant] that [she] had questions and concerns" regarding his coding instructions. (Tr. IV-139–40.) She also testified that she felt as though the Defendant was avoiding her, and explained that "it was a crazy . . . time" and that they were both busy. (Tr. IV-146.) Needle testified that she approached the Defendant because she was concerned about coding, and he told her "to do what [she] felt was appropriate" and she "asked him again what was appropriate because we were in a pandemic" and she had "never practiced in a pandemic before." (Tr. IV-151.) On cross-examination, however, she stated that she did not say that the Defendant told her to do what she felt was appropriate. (Tr. IV-200.)

Steven Carroll testified that he believed that level 4 appropriately described the patient encounters. (Tr. VIII-23.) He testified that the Defendant instructed providers to use level 4 coding, but that he did not feel any pressure to bill at a particular level. (Tr. VIII-22–23.) He

testified that he reviewed sources of information and explained that "the AMA puts out CPT coding guidelines on medical decision making. A big one was in September of 2021, during the COVID crisis." (Tr. VIII-22.) There were times when he would down-code from a level 4 to a level 3 when "it would get so busy, so hectic and chaotic, there may be documentation that is missing" such as vital signs. (Tr. VIII-23.) Carroll would consult with the Defendant and explain that there was missing documentation, which required Carroll to down-code the visit; the Defendant said: "That's perfectly fine." (*Id.*)

Carroll also agreed that the following does not describe a level 4 visit: "You speak to patient and chart as you go. Very simple charting. Remember this is virtual and [the patient] is there for one reason only-to be tested. Goal is to get them seen and out quickly (we want them in and out of the tent in under 5 minutes total). We are not there to solve complex medical issues, etc… Just to test them. ANY issues outside of that, refer them to Gambrills, their PMD, or the ER (if they look bad)." (Gov't Ex. 647; Tr. VIII-40–41, Carroll.) Carroll was shown medical records of a patient who needed a test for work and who was coded as a level 4; the "Care Plan" indicates that a rapid test and a PCR test were done, that the rapid test was negative, and that the patient was asked to follow CDC guidelines and to monitor their vitals. (Tr. VIII-42.) Carroll agreed that this visit and two other similar visits for the same patient should not have been coded as level 4 visits. (Tr. VIII-43–44.) However, he testified that, at the time, he believed it was the appropriate coding. (Tr. VIII-44.)

Suzanna Silva testified that the COVID-19 visits were typically level 4 visits because "the information that I would gather from the patient for the subjective portion of the exam, meaning the history, review of systems, family history, and those subjective portions, as well as the physical exam that I performed and the complexity of the decision making, was that of a level 4 visit." (Tr.

IX-106–107.) She believed that level 4 was appropriate for the COVID-19 testing encounters. (Tr. IX-107.) She testified that she was not selecting level 4 because the Defendant told her to, but because of "the complexity of the decision making, the thoroughness of the physical exam, and the history taking." (Tr. IX-107.) She did not feel pressure to code at a particular level. (Tr. IX-108.) She explained that she "rarely" coded at a level 3 and that she would only do so if it was "extremely straightforward, such as they simply needed a test for travel or work and were having absolutely no symptoms, I didn't need to take time consulting with them, helping them with any concerns, then I might code those as a level 3." (Tr. IX-110.) She testified that she "may have billed more 3s at Earleigh Heights given that my exam was more limited." (*Id.*)

e. Defendant

As discussed above, the Defendant testified that he determined that the coding levels were appropriate based on conversations with others. He also testified that, in the summer and fall of 2020, he reviewed the Novitas chart, which he had not previously reviewed but which Raymond gave to him. (Tr. X-113–14.) During his testimony, he walked through the Novitas chart to explain how he confirmed that the visits were appropriately coded. (Tr. X-113–31.) He explained that he understood COVID-19 to be an undiagnosed new problem with uncertain prognosis, testifying that "we don't have a diagnosis. It's undiagnosed. It's a new problem. And it's uncertain prognosis. People were dying, remember. The world was shut down. Because we didn't know what the prognosis was. So in my mind, by definition, that meant COVID met that. Didn't meet anything else." (Tr. X-126–27.)

During his testimony, he also walked through the 2021 CPT Manual medical decision making chart. (Tr. X-134–36.) He explained that, in the "Number and Complexity of Problems Addressed at the Encounter" column, he believed that COVID-19 was an undiagnosed new

problem with uncertain prognosis and that, in the "Amount and/or Complexity of the Data to be Reviewed and Analyzed" column, he believed that the encounters met the "Moderate" level, because there were two tests given and one test was reviewed. (*Id.*)

The Defendant also testified that he found an online scoring tool on the American Association for Professional Coders website (Def. Ex. 2-A), which he also used to assess the appropriate code. (Tr. X-140–41.) He explained that this also confirmed that level 4 was the appropriate code. (Tr. X-141.)

D. Five Charged Encounters

1. A.H. – Count 1

A.H.'s[18] claim represents Count 1 of the Indictment, with an office visit that occurred on March 25, 2021 and was billed to Medicare on March 29, 2021 as a 99204 visit. The Government called A.H. as a witness; the relevant provider did not testify at trial.

A.H. testified that she received a COVID test at the Earleigh Heights location. (Tr. II-103.) She received a test because she "woke up that morning with a sore throat" and, although she "ha[s] allergies and often ha[s] a sore throat[,]" her "husband had recently been released from the hospital and sent to a rehabilitation center" and she needed to confirm she did not have COVID before he came home. (Tr. II-103–104.) She did not have other symptoms and had not been exposed to COVID. (Tr. II-104.)

A.H. completed the registration material, and she described the encounter as follows:

> [T]hen she told me that she was going to swab each nostril and that I'd be receiving two phone calls, one that afternoon with the rapid test results and one in a few days with the laboratory test results. She asked me if I had any questions and I said no. And then she swabbed each of my nostrils and turned around to a table and did

[18] A.H. worked at CMS prior to retiring and had some familiarity with CPT codes. (Tr. II-102, A.H.)

> something that I couldn't see for a few minutes. When she finished, she turned around and said, you're finished. I said, thank you, and I drove out.

(Tr. II-106.)

A.H. testified that her medical records did not accurately summarize her visit. (Tr. II-110.) For instance, the medical records include a "Physical Exam" section, which indicates that the "[p]hysical was limited by this being a virtual exam during COVID-19 global Pandemic. Vitals are found on scanned images/Pt demographic forms. I was able to view the patient over a HD camera and using an HD TV set-up they were able to see me as well." (Gov't Ex. 403.) A.H. testified that no one gave her a physical exam, that she did not recall speaking to anyone on camera, and that no one gave her the advice listed in the records. (Tr. II-109–10.)

On cross-examination, A.H. was shown the "Patient Registration Form" in her records. (Gov't Ex. 403.) That document includes a list of symptoms, and the box for sore throat was checked. (*Id.*) The document also includes a "Medical History" section, and the boxes for diabetes, high blood pressure, and pulmonary disease/asthma were checked, while the box for heart disease was not checked. (*Id.*) A.H. agreed that she had these conditions, and that she probably provided this information when she was seen. (Tr. II-129.) Under "Reason for Testing" the box for "I have been exposed" was not checked, but a space for "Other" included "husband coming." (Gov't Ex. 403.) Finally, at the bottom of the document, there were handwritten notations, including: "T [temperature] 98.4"; "P [pulse] 86"; "O2 [oxygen saturation] 97"; "R [respiration] 16"; "Post meno." (*Id.*) Despite these handwritten notations, A.H. testified that no one took her temperature, pulse, oxygen saturation, or respiration. (Tr. 130–31.)

A.H. testified that she received the result of her rapid test, which was negative, via a phone call. (Tr. II-110–111.) A few days later, she received the result of her laboratory test, which was

also negative, also via a phone call that lasted about a minute. (Tr. II-111.) A.H.'s medical records indicate, for that call:

> This patient is called today by me to check on them and discuss their COVID PCR results with them. We spoke at length over the phone about their PCR results and what that means for them. We also discussed their overall health and wellbeing. They had the rapid and PCR tests performed when they were seen in person . . . . I am also checking in on them to ensure they are doing well. In excess of 32 minutes since they were last seen by us, in person, was spent in total on such things as: coordinating their care, arranging for testing, testing, processing their samples, resulting their samples, charting, communicating with the patient, communicating with the lab, answering questions, discussing options the patient has moving forward/continued quarantine and isolation/therapeutic options, etc.

(Gov't Ex. 403.) A.H. disagreed with the characterization of this call in her medical records. (Tr. II-112–13.)

Later, A.H. received an explanation of benefits from Medicare. A.H. believed that the charges were "clearly a mistake" and she "called the number that's shown on the explanation of benefits" which appeared to be "in Maine." (Tr. II-115.) A.H. explained that the person on the phone "told [her] that that's just what we do." (Tr. II-120.) A.H. then "found the website for reporting, reporting things to the Office of Inspector General, and I put everything in writing and submitted it." (Tr. II-123.)

Miscoe testified that A.H.'s visit was scored correctly as a level 4. (Tr. IX-7.) Further, Hill testified that the care provided was medically necessary and was "reasonable, necessary, and prudent." (Tr. VIII-102.)

2. D.M. – Count 3

D.M.'s claim represents Count 3 of the Indictment, with an office visit that occurred on May 10, 2021 and was billed to Medicare on May 12, 2021 as a 99204 level service. The Government called D.M. as a witness; the relevant provider did not testify at trial.

D.M. recounted her visit to the Earleigh Heights location. She testified that she wanted a

test because her mother-in-law was in a nursing home. (Tr. III-69.) On cross examination, she was shown a Triage Form that she had signed and dated in which she had circled "I have been exposed" as her "Reason for Testing" and agreed that it was her signature at the bottom of the page. (Gov't Ex. 404; Tr. III-74.)

D.M. testified that she completed the registration paperwork and then was swabbed for the COVID-19 tests. (Tr. III-67–68.) D.M. could not remember whether she was asked questions and she estimated that the encounter with the provider on the monitor lasted about five minutes. (Tr. III-69.) She testified that she tested negative, and that she received the results of the rapid test at the time of the encounter from the person who swabbed her nose and from the person on the monitor. (Tr. III-70–71.) D.M. testified that did not believe she received the results of the PCR test. (*Id.*) She testified that she believed she "called the county or something" for the results of the PCR test, and that she did not remember that interaction. (Tr. III-71.) D.M.'s medical records indicate that: "Pt informed about negative COVID 19 PCR. Denies acute complaints at this time. Unable to connect via video chat, waited 15+ minutes however unsuccessful. Communicated results via telephone." (Gov't Ex. 404.) D.M. agreed that this sounded accurate. (Tr. III-71–72, D.M.)

Miscoe reviewed D.M.'s chart and concluded that it was appropriately scored as a 99204 visit. D.M.'s medical records indicate that she presented for a visit on May 10, 2021, that she was exposed to COVID-19, that she was not experiencing symptoms, that she received a rapid test and a PCR test, that the rapid test results were received on May 10, 2021, and that the PCR test results were received on May 11, 2021. He noted that the chart reflected that there was a positive COVID-19 contact, but that "we would assume that in any event." (Tr. IX-3.) As he explained:

> [W]e have . . . the undiagnosed new problem because we don't have a diagnosis yet confirmed with uncertain prognosis. And then in the second column, we have three

> points in category one, two unique tests ordered and one reviewed. So that gets us moderate in two of the three columns, so the overall decision making is moderate. And I believe this was a new patient evaluation, so it's a 99204.

(Tr. IX-4.) He also testified that the review of the tests did not need to occur in front of the patients in order to count for moderate level decision making; the test only needed to be reviewed that same day. (Tr. IX-7.)

Further, Hill testified that the care provided was medically necessary and was "reasonable, necessary, and prudent." (Tr. VIII-102.)

3. J.J. – Count 4

J.J.'s claim represents Count 4 of the Indictment, with an office visit that occurred on March 2, 2021 and was billed to CareFirst on March 5, 2021 as a 99214 level service. The Government called J.J. as a witness; the relevant provider did not testify at trial.

J.J. testified that she went to the Earleigh Heights location on March 2, 2021 to get a COVID test. She described the overall encounter as follows:

> You go up. You park. You wait in line. You have people coming out of a Conex box to hand you a clipboard that you write down all your information. You wait in line until they call you into a tent . . . . You have somebody come out, swab you, and they flip a TV monitor around to speak with – I'm guessing it's some type of provider, to ask you a few questions. And then you leave.

(Tr. V-4.)

Her medical records indicated that "[p]atient is here to be tested due to an exposure to COVID-19." (Gov't Ex. 405 .) J.J. testified that she believed that "this incident was due to a work close contact." (Tr. V-8.) Her records also indicate, on a hand-completed Triage Form, that she circled the following symptoms: "nasal congestion"; "fatigue"; "headaches"; and "sweats." (Gov't Ex. 405.) It also noted that the "Reason for Testing" is "Symptoms" (rather than "I have been exposed"). (*Id.*) The Triage Form also indicates that she has pulmonary disease/asthma, and she

testified that she has asthma. (*Id.*) Her medical records also include vitals—although she testified that no vitals other than her temperature were taken. (*Id.*)

Miscoe reviewed J.J.'s chart and testified that 99214 is the correct CPT code for the visit. (Tr. VIII-200.) He noted that the chart includes the "chief complaint, history of present illness, review of systems" and that these are not "relevant to scoring of the level." (Tr. VIII-195.) He explained that what is relevant is that the "patient is here to be tested due to an exposure to COVID-19." (*Id.*) He further explained that "[e]xposed or not, I would still code it from a diagnostic perspective based on the reason for the encounter" because "[i]t's COVID testing, so it would be suspected exposure even if wasn't reported" and it would be coded with the ICD Z20.822 code for suspected contact with or exposure to COVID-19. (*Id.*) He explained that this is an "undiagnosed new problem with uncertain prognosis" which results in a "moderate" designation in the first column of the medical decision making chart. (Tr. VIII-197.) He explained that, because there were two diagnostic tests ordered—a rapid test and a PCR test—and because the results from one test—the rapid test—were received the same day, this results in a "moderate" designation in the second column of the medical decision making chart. (Tr. VIII-195–198.)

Further, Hill testified that the care provided was medically necessary and was "reasonable, necessary, and prudent." (Tr. VIII-102.)

4. S.T. – Count 5

S.T's claim represents Count 5 of the Indictment, with an office visit that occurred on April 19, 2021 and was billed to CareFirst on April 28, 2021 as a 99204 level service. The Government called S.T. as a witness; the relevant provider did not testify at trial.

S.T. testified, in April 2021, she and her three children were tested because there was a COVID outbreak at their daycare. (Tr. IV-99.) She explained that someone took her temperature

and put a device on her finger and that "they might have asked [] a few questions" but that she did not remember. (Tr. IV-101.) Next, "they would swab [] both nostrils" and then she "went up to see the doctor or the provider on the screen." (Tr. IV-101.) She explained that the provider asked a few questions, such as "do you have any symptoms" and "why are you here." (Tr. IV-101.) She explained that she spent "[f]ive, ten minutes" with the provider, which included the provider seeing her three children. (Tr. IV-101–02.) She explained that she had to "take them each [] out of their car seat to be able to see them on camera." (Tr. IV-102.)

S.T. testified that she received a rapid and a PCR test. (Tr. IV-102.) She believed she received the results of her rapid and PCR tests through "a chart that you could look at." (Tr. IV-103.) S.T. testified that she spoke to someone on the phone when one of her daughters had tested positive and that the phone call lasted less than five minutes. (*Id.*) She testified that she did not believe she received a phone call about her test results. (*Id.*) With respect to the results, S.T.'s medical records reflect that: "This patient is called today by me to check on them and discuss their COVID PCR results with them. We spoke at length over the phone about their PCR results and what that means for them. We also discussed their overall health and wellbeing." (Gov't Ex. 408.) S.T. testified that she did not recall that conversation. (Tr. IV-104.) The Government also introduced the medical records of S.T.'s children. (Gov't Exs. 409, 410, 413.) The records reflect similar language to the language in S.T.'s records regarding the phone call. S.T. testified that she did not recall having any conversations about negative test results. (Tr. IV-107.)

Miscoe testified that S.T.'s visit was scored correctly as a level 4 visit. (Tr. IX-7.) Further, Hill testified that the care provided was medically necessary and was "reasonable, necessary, and prudent." (Tr. VIII-102.)

5. W.R. – Count 2

W.R.'s claim represents Count 2 of the Indictment, with an office visit that occurred on April 23, 2021 and was billed to Medicare on May 3, 2021 as a 99204 level service. W.R. is S.T.'s father, and S.T. testified regarding W.R.'s visit. In addition, the relevant provider, Wrona, also testified.

S.T. testified that, after one of her children tested positive, her father W.R. was tested for COVID. (Tr. IV-107.) She explained that he was tested at Earleigh Heights and that the process was the same as the process she described for herself and her children, that the provider requested to see her father's face, and that the time spent with the provider on screen was about five minutes. (Tr. IV-108.)

On direct examination, Wrona was asked whether she did the physical exam that was noted in W.R.'s medical record. (Tr. V-204.) She responded: "No, I did not do all of it. Some of it would be like, yes, they're awake, alert, and that sort of thing. But when it says under ENT, i.e., 'the pharynx is without exudates,' I would not have seen that." (*Id.*) She also testified that W.R. did not get out of the car, and was also asked: "What about the review of systems? Could you do a review of systems if the patient did not get out of the car?" to which she responded "Yes." (Tr. V-204–05.) W.R.'s medical records include a "Care Plan" which indicates that: "In this patient with possible Covid-19 exposure, [a] rapid Covid test was done and was negative, a confirmatory PCR Covid swab was sent. I've asked this patient to follow current CDC guidelines for infection and transmission control. Home quarantine pending results. Also advised patient to monitor AM and PM temps and respiratory symptoms. Rest, maintain good fluid hydration, Tylenol prn fever and body[ ]aches. If any symptoms of DOE, SOB, chest pain, palpitations, N, V, D, F/U with medical provider urgently. Full PPE was worn during encounter. All questions asked were

answered." (Gov't Ex. 407.) Wrona agreed that this was a templated care plan and that it did not appear that she had made any modifications to the care plan. (Tr. V-205.) She also testified that she was likely not in PPE since this was a remote visit but that any error would have been inadvertent. (Tr. V-205; Tr. VI-54.)

Miscoe testified that W.R.'s visit was scored correctly as a level 4 visit. (Tr. IX-7.) Further, Hill testified that the care provided was medically necessary and was "reasonable, necessary, and prudent." (Tr. VIII-102.)

II. Legal Standards

A. Federal Rule of Criminal Procedure 29

Under Rule 29, "the court on the defendant's motion must enter a judgment of acquittal for any offense for which the evidence is insufficient to sustain a conviction." "Sufficiency-of-the evidence review involves assessment by the courts of whether the evidence adduced at trial could support any rational determination of guilty beyond a reasonable doubt." *United States v. Powell*, 469 U.S. 57, 67 (1984).

The "critical inquiry" in determining whether a Rule 29 motion should be granted is "whether the record evidence could reasonably support a finding of guilt beyond a reasonable doubt." *Jackson v. Virginia*, 443 U.S. 307, 318 (1979). As the Fourth Circuit has explained:

> [A] judgment of acquittal is appropriate when the evidence is so deficient that acquittal is "the *only* proper verdict." *Tibbs v. Florida*, 457 U.S. 31, 42 (1982). That is, if the evidence is so insufficient that *no* rational trier of fact could convict, the court should enter a judgment of acquittal.

United States v. Rafiekian ("Rafiekian II"), 68 F.4th 177, 186 (4th Cir. 2023).

A defendant challenging the sufficiency of the evidence "bears a heavy burden." *United States v. Beidler*, 110 F.3d 1064, 1067 (4th Cir. 1997) (citation and quotations omitted). "The Court reviews whether there is substantial evidence to support the jury verdict, meaning that . . .

the record must demonstrate a lack of evidence from which a jury could find guilt beyond a reasonable doubt[.]" *United States v. Tillmon*, 954 F.3d 628, 637 (4th Cir. 2019) (quotations, citations, and alterations omitted); *see also United States v. Burgos*, 94 F.3d 849, 862 (4th Cir. 1996) ("[I]n the context of a criminal action, substantial evidence is evidence that a reasonable finder of fact could accept as adequate and sufficient to support a conclusion of a defendant's guilt beyond a reasonable doubt.").

In determining whether to grant a judgment of acquittal, the court views the evidence and inferences therefrom in the light most favorable to the government. *Rafiekian II*, 68 F.4th at 186. Further, the jury, not the court, "weighs the credibility of the evidence and resolves any conflicts in the evidence presented" when such determinations need to be made. *Burgos*, 94 F.3d at 862. "Likewise, determinations of credibility are within the sole province of the jury and are not susceptible to judicial review." *Id.* at 863 (citation and quotations omitted).

B. Federal Rule of Criminal Procedure 33

Rule 33 allows a district court to "vacate any judgment and grant a new trial if the interest of justice so requires." "When the evidence weighs so heavily against the verdict that it would be unjust to enter judgment, the court should grant a new trial." *United States v. Arrington*, 757 F.2d 1484, 1485 (4th Cir. 1985); *see also United States v. Souder*, 436 F. App'x 280, 289 (4th Cir. 2011) ("[T]he trial court may grant relief if it determines that the evidence—even if legally sufficient to convict—weighs so heavily against the verdict that it would be unjust to enter judgment."). The "standard for jettisoning a jury verdict in favor of a new trial" is "demanding," and courts must exercise their discretion to grant a new trial "sparingly." *United States v. Millender*, 970 F.3d 523, 531–32 (4th Cir. 2020).

There are important differences between a court's decision to grant a Rule 29 motion and

a court's decision to grant a Rule 33 motion. "In assessing the former, the trial court must find that the evidence was legally insufficient to support the conviction (i.e., that no rational jury could have voted to convict on the government's evidence); as to the latter, the trial court may grant relief if it determines that the evidence—even if legally sufficient to convict—weighs so heavily against the verdict that it would be unjust to enter judgment." *Souder*, 436 F. App'x at 289. As the Fourth Circuit has explained:

> When the motion [for a new trial] attacks the weight of the evidence, the court's authority is much broader than when it is deciding a motion to acquit on the ground of insufficient evidence. In deciding a motion for a new trial, the district court is not constrained by the requirement that it view the evidence in the light most favorable to the government. Thus, it may evaluate the credibility of the witnesses.

Arrington, 757 F.2d at 1485.

A "court may properly conclude that a new trial is warranted based on the 'cumulative' weight of the evidence rather than by separately rejecting each individual offer of proof by the government." *Rafiekian II*, 68 F.4th at 187 (citing *United States v. Campbell*, 977 F.2d 854, 860 n.6 (4th Cir. 1992)). In addition, "disagreement with the jury's inferences regarding the evidence can support the district court's decision to grant a new trial." *Rafiekian II*, 68 F.4th at 188.

The Fourth Circuit has explained that "in determining whether a new trial is warranted, the district court—sitting as a thirteenth juror—conducts its own assessment of the evidence, unconstrained by any requirement to construe the evidence in the government's favor." *Rafiekian II*, 68 F.4th at 186 (citations, quotations, and alterations omitted). However, this "thirteenth juror" language is tempered by the fact that "[m]erely believing that the case could have come out the other way is not enough to warrant a new trial." *Id.*

C. 18 U.S.C. § 1347

The Government charged the Defendant with violating 18 U.S.C. § 1347, which provides:

> (a) Whoever knowingly and willfully executes, or attempts to execute, a scheme or artifice—
>
> > (1) to defraud any health care benefit program; or
> >
> > (2) to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program,
>
> in connection with the delivery of or payment for health care benefits, items, or services, shall be fined under this title or imprisoned not more than 10 years, or both.

Thus, as the Court instructed the jury at trial, the Government was required to prove beyond a reasonable doubt that (1) "there was a scheme to defraud or a scheme to obtain money or property by means of materially false or fraudulent pretenses, representations, or promises in connection with the delivery of or payment for health care benefits, items, or services"; (2) "the defendant knowingly and willfully executed or attempted to execute that scheme with the intent to defraud"; and (3) the "target of the scheme was a health care benefit program." (*See* Tr. XI-128 (Jury Instruction 38).) Further, as the Court instructed the jury, the Government was required to prove, for each of the counts charged in the Indictment, that "the claim charged in that count . . . was false or fraudulent as to a material fact or matter." (*See* Tr. XI-127 (Jury Instruction 39).) The Court explained that a "representation is fraudulent if it was falsely made with the intent to deceive." (*Id.*)

With respect to the first element, the Fourth Circuit has explained that, "[i]n considering whether there existed a scheme to defraud, we must look to the common-law understanding of fraud, which we have interpreted to include acts taken to conceal, create a false impression, mislead, or otherwise deceive in order to prevent the other party from acquiring material information." *United States v. Perry*, 757 F.3d 166, 176 (4th Cir. 2014) (citations, quotations, and alterations omitted). Further, the Fourth Circuit has explained, in the context of a vagueness

challenge to 18 U.S.C. § 1347(a)(2), that the provision "gives ample notice that criminal liability attaches to those who *knowingly* give a representation that could be shown to be objectively *false* about services performed for the purpose of obtaining money." *United States v. Janati*, 237 F. App'x 843, 847 (4th Cir. 2007) (emphasis in original).

With respect to the second element, "[t]he health care fraud statute requires a specific intent to defraud[,]" *id.*, which "may be inferred from the totality of the circumstances and need not be proven by direct evidence." *United States v. McLean*, 715 F.3d 129, 138 (4th Cir. 2013) (quotation marks omitted).

There is no dispute regarding the third element, as both parties agreed that CareFirst and Medicare are health care benefit programs with the meaning of 18 U.S.C. § 1347.

III. Analysis

The crux of the Defendant's argument is that the evidence was insufficient to establish that the level 4 codes inaccurately described the patient encounters and that the jury therefore had no reasonable basis for concluding that the five charged counts constituted executions of a scheme. (*See generally* ECF No. 78.) Thus, the Defendant argues that he is entitled to an acquittal on all five counts. (*Id.* at 9–31.) Alternatively, the Defendant argues that the evidence weighs so heavily against the verdict that he is entitled to a new trial. (*Id.* at 31–34.) The Government counters that it adduced sufficient evidence for the jury to find that the patient encounters were not level 4 encounters, and that the weight of the evidence does not merit a new trial. (*See generally* ECF No. 85.)

The Court finds that the Government did not carry its burden to prove beyond a reasonable doubt the falsity of the level 4 billing, and finds that the evidence in this case was insufficient to establish, beyond a reasonable doubt, that the level 4 codes used to describe the five encounters

that drew charges in the Indictment were false or fraudulent. The Court will therefore grant the Defendant's Motion for Judgment of Acquittal. The Court will also conditionally grant the Defendant's alternative Motion for a New Trial.

A. The Government's Theory

The Indictment alleges that the Defendant executed a scheme to defraud by "submitting and causing the submission of false and fraudulent claims to Medicare, Medicaid, TRICARE, Commercial Insurers, and the HRSA COVID-19 Uninsured Program for E/M Services during the COVID-19 pandemic that were medically unnecessary, not provided as represented, and ineligible for reimbursement." (Indictment ¶ 29.) The Indictment further explains that the Defendant "required that the COVID-19 tests and the report of results be bundled, i.e., required to be billed in combination with more lucrative, but medically unnecessary, services, such as E/M Services, that were purportedly of a 30-minutes or longer duration, or involving moderate or high levels of medical decision making, but did not in fact occur as represented." (*Id.* ¶ 30.e.) It explains that the Defendant "instructed providers and other employees to bill the encounters as moderate complexity E/M Services even though such encounters did not occur as represented." (*Id.* ¶ 30.f.)

The five counts in the Indictment charge that, for five patients that were seen in March, April, and May of 2021, the Defendant "submitted and caused the submission of the [ ] false and fraudulent claims to Medicare and CareFirst Blue Cross Blue Shield for E/M Services that were medically unnecessary, not provided as represented, and ineligible for reimbursement[.]" (*Id.* ¶ 31.)

The Government's theory of fraud in this case was not a model of clarity. For instance, the Government presented no evidence at trial regarding the medical coding for payors other than Medicare and CareFirst despite the Indictment's reference to false and fraudulent claims submitted

by other payors. As the Court explained at trial, there was evidence that different insurance payors viewed coding differently, and thus, the Government was required to present evidence with respect to each relevant payor. (*See* Tr. VI-63–70.) The Government did not present any such evidence and, as a result, the Court did not allow the Government to present summary evidence regarding claims to payors other than Medicare and CareFirst. (*Id.* (the Court explaining that, in a criminal case, the "proof has to be on all fours all the way through" and that it was not "that close of a call").)

Further, although the Indictment refers to medically unnecessary services bundled with COVID-19 tests and although the Government referred to "unnecessary level 4 office visits" in its opening argument (Tr. I-27), the Government appears to have abandoned its medical necessity theory. For instance, in his briefing, the Defendant explains that the Government presented no evidence supporting the theory that the provider visits were not medically necessary. (ECF No. 78 at 10 n.8.) The Government does not respond to this argument at all, and does not even mention medical necessity in its briefing. (*See generally* ECF No. 85.) Further, at trial, during the Defendant's Rule 29 motion after the close of the Government's evidence, the Government likewise did not refute the Defendant's arguments that the Government presented no evidence with respect to medical necessity. (*See* Tr. VII-107–08, Tr. VII-113–17.) In any event, the Court finds that the Government presented no evidence with respect to the issue of medical necessity.

As crystallized at trial and by the parties' briefing, the Government's theory of the Defendant's fraudulent scheme with respect to the five charged counts was that the Defendant billed for level 4 services when some lower level of service was provided. This practice is also known as "upcoding." As the Government explains in its briefing, "[b]y instructing his providers to code every COVID-19 testing patient for a level 4 office visit in addition to the COVID-19 test,

the Defendant was telling Medicare and other insurers that every patient was receiving an 'office or other outpatient visit for the evaluation and management of a [new or existing] patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making.'" (ECF No. 85 at 5.) As the Defendant explains, "[t]he *sine qua non* of the alleged scheme was [] that the codes did not describe the services" and "[e]vidence from which the jury could find that the codes were wrong was therefore essential; without it, the jury could not convict." (ECF No. 78 at 10; *see also* Tr. VI-66 (the Court explaining that "the Government seems to accept the premise that there is a threshold requirement to demonstrate a misapplication of codes in order for the defendant to be guilty as charged").)

It follows that, to prove the scheme, the Government was required to prove beyond a reasonable doubt that the level 4 coding was false. As noted above, the Court instructed the jury that the Government was required to prove, for each of the charged counts, that "the claim charged in that count . . . was false or fraudulent as to a material fact or matter[.]" (*See* Tr. XI-127 (Jury Instruction 39).)

B. Proof Required

The Court pauses here to address the Government's argument that "[t]he jury could reasonably infer that the claims were false because the evidence of the Defendant's intent showed that he intended to submit false claims." (ECF No. 85 at 16–17.) This argument improperly collapses two of the three elements the Government was required to prove beyond a reasonable doubt. In many cases, there will of course be overlap in the evidence the Government uses to prove the existence of a scheme and a defendant's intent to defraud. However, the Government is required to prove beyond a reasonable doubt each element of the crime. *In re Winship*, 397 U.S. 358, 364 (1970) (explaining that "the Due Process Clause protects the accused against conviction

except upon proof beyond a reasonable doubt of *every fact necessary* to constitute the crime with which he is charged." (emphasis added)). This is a bedrock principle of criminal law, and proof of the Defendant's subjective intent cannot stand in for proof of falsity. The Government's argument is perilously close to advocating for a conviction to stand based on the Defendant's *mens rea* alone.

In this case, proving every element of the crime includes proving beyond a reasonable doubt *both* the Defendant's specific intent to defraud *and* the existence of a scheme to obtain money by means of materially false or fraudulent pretenses. *See United States v. Bajoghli*, 785 F.3d 957, 962, 964 (4th Cir. 2015) (explaining that "[a] 'scheme to defraud' is [ ] an element of the offense" and that "[t]he government has the burden of proving a scheme to defraud and [the defendant's] knowing and willful conduct in executing the scheme" (emphasis omitted)); (Tr. XI-125–28 (Jury Instructions 39 and 40 explaining that "[t]he first element that the government must establish beyond a reasonable doubt is that there was a scheme to defraud or a scheme to obtain money or property by means of materially false or fraudulent pretenses, representations, or promises" and that "[t]he second element that the government must establish beyond a reasonable doubt is that the defendant knowingly and willfully executed or attempted to execute that scheme with the intent to defraud").)[19]

Here, there is little question that the appropriate CPT code for the patient encounters in this case is ambiguous, as discussed in greater detail below. Terms like "moderate" or "undiagnosed new problem with uncertain prognosis" in this context are unfamiliar to a lay person and are subject to various meanings. This case therefore presents difficult questions: where the guidance is

[19] The parties included these instructions in their Joint Proposed Jury Instructions. (ECF No. 34 at 33–34.)

ambiguous, what does it mean for a statement to be "false or fraudulent" beyond a reasonable doubt? At what point is a representation "objectively false"?

To answer these questions, the Court finds guidance in the opinion deciding *United States v. Harra*, which is reported at 985 F.3d 196 (3d Cir. 2021). That case involved ambiguous reporting requirements regarding reporting past due loans. *Id.* at 205–06. The court held that "to prove falsity beyond a reasonable doubt" in the context of an ambiguous reporting requirement, "the Government must prove either that its interpretation of the reporting requirement is the only objectively reasonable interpretation or that the defendant's statement was also false under the alternative, objectively reasonable interpretation." *Id.* at 204. In so doing, the court rejected the government's argument that "the Government's burden as to falsity is simply to prove that a defendant understood an ambiguous reporting requirement to mean what the Government says it means and, in light of that meaning, intended to lie." *Id.* at 211. "In the false statement context, because falsity and knowledge are distinct elements, this means the Government must prove a statement was false beyond a reasonable doubt, regardless of the defendant's subjective intent to lie." *Id.* The court explained that it was "guided by [a] due process principle: the requirement that potential defendants be given 'fair warning' of what conduct could give rise to criminal liability" and that such principles "apply with equal force when a defendant is criminally charged as a result of noncompliance with agency regulations or guidance." *Id.* at 212–13.

The court went on to conclude that the reporting requirement was ambiguous and that the government had not carried its burden of "proving beyond a reasonable doubt that either the alternative interpretation was unreasonable or that Defendants' statements were false even under that alternative and reasonable interpretation." *Id.* 219–20. The court explained that "other than relying on the purported 'ordinary meaning' of 'contractually past due,' the Government offer[ed]

no evidence that [the defendant's] interpretation is *unreasonable*—which it must in order to meet its burden to prove falsity." *Id.* at 220 (emphasis in original); *see also id.* at 220 n.18 ("Had the Government, for example, offered evidence that 'contractually past due' was an industry term of art with a widely accepted meaning, it may have been able to convince a jury that the alternative interpretation was unreasonable . . . . But in the absence of any such evidence, there was insufficient evidence from which a jury could conclude that the Government's interpretation is the only reasonable reading of the reporting requirement."). The court ultimately vacated the convictions based on the purportedly false statements, and ordered a new trial on other counts—including a securities fraud count, which has similar elements to 18 U.S.C. § 1347—because those counts rested on an alternative theory of liability.

Other circuit courts have concluded similarly. *See, e.g.*, *United States v. Migliaccio*, 34 F.3d 1517, 1525 (10th Cir. 1994) ("In cases arising under 18 U.S.C. § 1001, which criminalizes making false statements to a government agency, the government bears the burden to negate any reasonable interpretations that would make a defendant's statement factually correct where reporting requirements are ambiguous . . . . This reasoning applies equally well to the false statement element of mail fraud. It necessarily follows that, where the evidence supports a defendant's position, the jury must be instructed concerning reasonable interpretations of ambiguous requirements and the government's ensuing burden."); *United States v. Whiteside*, 285 F.3d 1345, 1351 (11th Cir. 2002) ("In a case where the truth or falsity of a statement centers on an interpretive question of law, the government bears the burden of proving beyond a reasonable doubt that the defendant's statement is not true under a reasonable interpretation of the law."); *United States v. Prigmore*, 243 F.3d 1, 17–18 (1st Cir. 2001) ("[T]here has been no crime if the statements were not false . . . under an objectively reasonable interpretation of the law imposing

the duty."); *United States v. Johnson*, 937 F.2d 392, 399 (8th Cir. 1991) ("[T]he government must negative any reasonable interpretation that would make the defendant's statement factually correct." (quoting *United States v. Anderson*, 579 F.2d 455, 460 (8th Cir. 1978))). And while the Fourth Circuit has taken a slightly different approach when reviewing a perjury conviction, it was on facts that were readily distinguishable from the case at bar.[20] The Court finds that the

[20] In *United States v. Sarwari*, 669 F.3d 401 (4th Cir. 2012), the Fourth Circuit explained in a footnote that "[m]ore than thirty years ago, we suggested, in dicta, that a false statement conviction 'could not stand' if a defendant's statement accords 'with a reasonable construction' of the information sought." *Id.* at 407 n.3 (citing *United States v. Race*, 632 F.2d 1114, 1116 (4th Cir. 1980)). The Fourth Circuit went on to explain that, "[g]iven the clarity and narrowness of the *Bronston* defense, we must disavow the *Race* dicta." *Id.* The *Bronston* defense refers to the "literal truth" defense whereby an individual cannot be convicted of perjury when the allegedly false statement was "literally true but not responsive to the question asked and arguably misleading by negative implication." *See Bronston v. United States*, 409 U.S. 352, 353 (1973). The *Race* dicta provided that defendants could not be convicted of making a false statement where the statement "may be said to be accurate within a reasonable construction of the contract" and that "this is so because one cannot be found guilty of a false statement under a contract beyond a reasonable doubt when his statement is within a reasonable construction of the contract." *Race*, 632 F.2d at 1120.

Sarwari does not foreclose the Court's reliance on *Harra* in this case. In *Sarwari*, the defendant was convicted of willfully and knowingly making a false statement on a passport application in violation of 18 U.S.C. § 1542 when he indicated that he was the applicants' father, but was actually their stepfather. *Sarwari*, 669 F.3d at 404. The Fourth Circuit concluded that *Bronston* did not apply because the defendant's statements were not "undisputedly literally true." *Id.* at 406–07. The court explained that, where a question is "fundamentally ambiguous," there can be no false statement prosecution, but that where a question is "susceptible to multiple interpretations, and a defendant's answer is true under one understanding of the question but false under another, the fact finder determined whether the defendant knew his statement was false." *Id.* at 407. The court explained that requesting identification of a child's "father" is "possibly ambiguous" but concluded that the jury could have concluded beyond a reasonable doubt that the defendant "understood the inquiry made by the passport application as the Government itself did and answered the question posed—identification of the children's father—falsely." *Id.* at 410.

The facts in *Harra* are more closely analogous to the facts in this case. In *Sarwari*, the Court assessed a "possibly ambiguous" question: was the defendant the applicants' father or not? He was not, and the court concluded that the jury determined that the defendant had understood the question and answered it falsely. It is rarely conceptually difficult for a factfinder to determine whether the answer to a straightforward yes-or-no question is literally true. Here, by contrast, the truth or falsity of the Defendant's selection of the level 4 billing codes turns not on whether the Defendant reasonably interpreted a single yes-or-no question, but on the reasonableness of the Defendant's interpretation of a raft of complex and constantly shifting guidance and regulations. Resolving the truth or falsity in this context is a more challenging endeavor, and a conviction cannot lie on the basis of the Defendant's subjective understanding of the regulations alone, in the absence of evidence showing that that interpretation was objectively unreasonable. And in any event, in this case, as discussed in more detail below, the coding guidance is unquestionably ambiguous.

Further, as the *Harra* court also noted, *Sarwari* was decided in the context of a false statement involving a passport application form, and discussed scienter, rather than falsity, the element on which the Government stumbles in this case. *See Harra*, 985 F.3d at 214 n.13 (explaining that the Fourth Circuit has "suggested, in [a] false statement case[] involving application forms, that as long as there is sufficient evidence that the Government and the defendant had the same meaning in mind, the prosecution has satisfied its burden to prove falsity" but that this case "do[es] not grapple with falsity at all—only with scienter.").

Government was required to prove that the Defendant's interpretation of the coding guidance was not reasonable.

C. Rule 29

The principal thrust of the Government's argument with respect to whether the level 4 billing was false is that common sense dictates the result in this case. However, this case is not just about common sense. Rather, it is about a complex set of rules—as contained in the CPT Manual and related guidance—and the extent to which the Defendant complied with those rules. There can, of course, be no crimes if the Defendant complied with those rules.

Specifically, with respect to the five charged counts, the Defendant's conviction depends on whether billing those patient visits as level 4 visits complied with the 2021 CPT Manual and other guidance in effect at the time. It was therefore essential that the Government present evidence that would allow a reasonable jury to conclude that billing these visits as level 4 visits was false beyond a reasonable doubt. The Government did not carry its burden, and no reasonable jury could have so concluded.

1. The CPT Manual and COVID-19 Coding Guidance are Ambiguous[21]

The Court first addresses the Government's argument that the CPT Manual is "written in English" and that billing the COVID-19 testing visits as level 4 visits does not comport with a

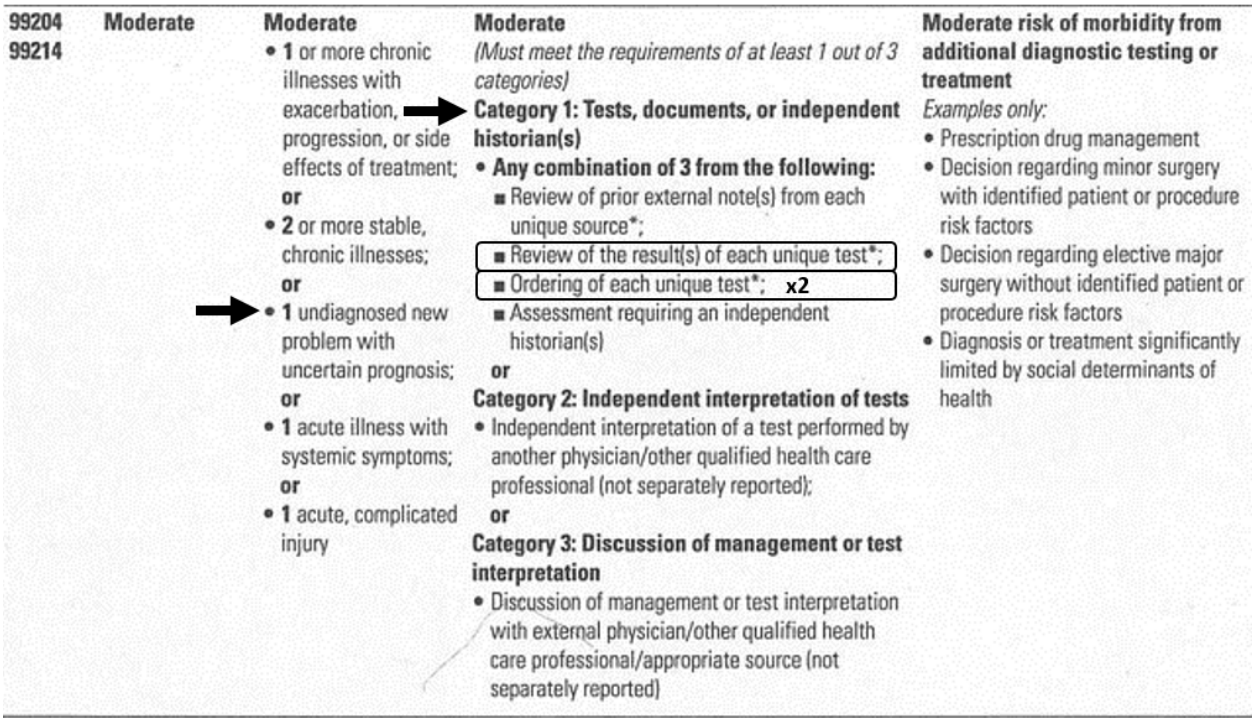
[21] The Court does not suggest that an 18 U.S.C. § 1347 charge premised on a violation of the CPT manual is impermissibly vague. The Court recognizes that the Fourth Circuit has addressed vagueness challenges to 18 U.S.C. § 1347 by relying on the statute's *mens rea* requirement. *See McLean*, 715 F.3d at 137 ("[T]he statute's *mens rea* requirement mitigates any ambiguity arising from the lack of clear medical guidance" and "[the defendant] could only be convicted if the government proved beyond a reasonable doubt that he acted 'knowingly and willfully' to defraud insurers, which necessarily entails proof that he knew the [certain medical procedures] were unnecessary."); *see also Janati*, 237 F. App'x at 847 ("The health care fraud statute requires a specific intent to defraud . . . and the indictment charged that the Janatis *knowingly* misrepresented that Dr. Janati had performed services that qualified for billing at the Code 99215 level. Any opacity of the CPT manual would have to be so great that one could not *know* the proper code and therefore could not *knowingly* record an improper code. But then, the Janatis' vagueness challenge would be no more than a challenge to the sufficiency of the evidence of their mental states." (emphasis in original)). These cases focus on the *mens rea* required under 18 U.S.C. § 1347 in the context of vagueness challenges, and do not specifically address the threshold issue of falsity.

"common-sense reading of the CPT Code and its accompanying resources." (ECF No. 85 at 9.) The jury was, of course, entitled to rely on its common sense in rendering its verdict. *See Huffington v. Nuth*, 140 F.3d 572, 583 (4th Cir. 1998) (explaining that "a jury may properly rely on their common sense" (citation and quotations omitted)). Indeed, the Court instructed the jury to do just that. (*See, e.g.*, Tr. XI-108 (Jury Instruction 14 explaining that "[y]ou infer on the basis of reason and experience and common sense from an established fact . . . the existence or the nonexistence of some other fact[.]").)

However, in the context of this complex medical coding framework, the jury could not only rely on its common sense. Rather, the jury in this case had to be given tools to aid in decoding that complicated framework. Coding in this context is beyond the ken of a layperson, no matter their common sense. In other words, lay jurors asked to interpret and apply the specialized CPT codes relevant here required input—in the form of evidence, expert or otherwise—to augment and inform their common sense. Without such input, the jury was left to impermissibly speculate about what a level 4 visit required and, consequently, whether the Defendant's statements that the COVID-19 testing visits were level 4 visits were false. In short, the Government cannot merely point to the plain English meaning of terms in the CPT Manual and argue that the level 4 coding did not comport with common sense.

a. The CPT Manual

As explained above, to qualify as a level 4 visit, a visit must meet the thresholds in two of the three columns in the below chart.



99204 **99214**	**Moderate**	**Moderate** • **1** or more chronic illnesses with exacerbation, progression, or side effects of treatment; **or** • **2** or more stable, chronic illnesses; **or** • **1** undiagnosed new problem with uncertain prognosis; **or** • **1** acute illness with systemic symptoms; **or** • **1** acute, complicated injury	**Moderate** *(Must meet the requirements of at least 1 out of 3 categories)* **Category 1: Tests, documents, or independent historian(s)** • **Any combination of 3 from the following:** ▪ Review of prior external note(s) from each unique source*; ▪ Review of the result(s) of each unique test*; ▪ Ordering of each unique test*; **x2** ▪ Assessment requiring an independent historian(s) **or** **Category 2: Independent interpretation of tests** • Independent interpretation of a test performed by another physician/other qualified health care professional (not separately reported); **or** **Category 3: Discussion of management or test interpretation** • Discussion of management or test interpretation with external physician/other qualified health care professional/appropriate source (not separately reported)	**Moderate risk of morbidity from additional diagnostic testing or treatment** *Examples only:* • Prescription drug management • Decision regarding minor surgery with identified patient or procedure risk factors • Decision regarding elective major surgery without identified patient or procedure risk factors • Diagnosis or treatment significantly limited by social determinants of health

***Note: arrows, boxes, and "x2" supplied to illustrate.**

Thus, a level 4 visit includes one at which the patient (1) presented with "1 undiagnosed new problem with uncertain prognosis" (i.e., the third bullet in the first column above) and (2) received two unique tests and for whom the provider reviewed the results of one test (i.e., the "Category 1" section of the second column).

To determine whether a particular patient visit qualified as a level 4 visit, the jury was required to apply the terms "moderate level medical decision making" and "undiagnosed new problem with uncertain prognosis" to the COVID-19 testing visits that occurred at DEC. The Government argues that the CPT Manual is "written in English" (ECF No. 85 at 9) and, during its closing argument, it argued that "the defendant's going to . . . try to explain to you why words written in English don't mean what you think they mean." (Tr. XI-15.) However, the term "moderate level medical decision making" simply does not retain its plain English meaning in the

medical coding context. The Government's own expert witness agreed that "determining the complexity of medical decision making" is "not just something that a coder or provider determines based on the words" in the CPT Manual. (Tr. I-191, Quindoza.)

Rather, per the 2021 CPT Manual, medical decision making "is defined by three elements": "[t]he number and complexity of problem(s) that are addressed during the encounter"; "[t]he amount and/or complexity of the data to be reviewed and analyzed"; and "[t]he risk of complications and/or morbidity or mortality of patient management decisions[.]" (2021 CPT Manual at 14.) The 2021 CPT Manual provides a chart that "is a guide meant to assist in selecting the level of MDM[.]" (*Id.* at 15.) There was no testimony or other evidence presented at trial that suggested that providers were not to use this definition of medical decision making or this chart to guide their coding decisions.

The chart, in turn, uses various terms—many of which would be unfamiliar to a lay person—to define the levels of medical decision making. As relevant to the charges in this case, the chart provides that a visit involves "moderate" medical decision if a patient presents with "1 undiagnosed new problem with uncertain prognosis" and if the visit includes "[a]ny combination of 3 from the following: Review of prior external note(s) from each unique source; Review of the result(s) of each unique test; Ordering of each unique test; Assessment requiring an independent historian(s)[.]" (2021 CPT Manual at 16.) The Manual specifies that "[e]ach unique test . . . is counted to meet [the] threshold number." (*Id.* at 14.) There was no evidence presented at trial to suggest that ordering two COVID-19 tests and reviewing the results of one of those tests does not meet this threshold. Indeed, it would seem that this falls squarely within the thresholds based on the description in the CPT Manual.

The term "undiagnosed new problem with uncertain prognosis" is defined as "[a] problem in the differential diagnosis that represents a condition likely to result in a high risk of morbidity without treatment. An example may be a lump in the breast." (2021 CPT Manual at 13.) "Morbidity" is defined as: "[a] state of illness or functional impairment that is expected to be of substantial duration during which function is limited, quality of life is impaired, or there is organ damage that may not be transient despite treatment." (*Id.* at 14.) There is no definition of "differential diagnosis" in the CPT Manual, and none was provided by any witness.

There cannot be any serious dispute that selecting the correct CPT code in this context is somewhat ambiguous. The Government itself, in its closing argument, explained to the jury that "you may be asking yourself, what [code] should have been billed in [these] cases, and the good news for you is you don't have to figure that out. You don't have to decide if it's a 3 or a 2 or a 1. The only thing you have to decide is that Dr. Elfenbein intended to get money that he wasn't entitled to and that these visits, including our five count beneficiaries, were not a level 4." (Tr. XI-28.) The Court of course understands the Government's point in making this argument was that, whatever the correct code, it was certainly not a level 4. However, the argument also reflects a critical point: that there is ambiguity in assigning the correct code. This point was also reflected in Sinagra's testimony, when she explained that auditors do not necessarily make the same findings with respect to claims, and that it would not be out of the ordinary to have a one-level difference between coding in audits. (Tr. V-150.)

Given the foregoing, while the Government is correct that the CPT Manual is literally written in English, it strains logic to suggest that a jury could rely on common sense to understand under what circumstances a patient encounter could qualify as a level 4 visit. Where terms have been defined in such a specific manner in such a specific context, the Government cannot then

urge that the jury should apply a plain-English understanding to the terms. Rather, the Government had to present evidence from which a reasonable juror could come to understand these terms and how they are applied in the medical coding arena.

b. The COVID-Specific Guidance

This ambiguity was particularly acute in the context of the COVID-19 pandemic. (*See, e.g.*, Tr. IX-19 (Miscoe testifying that "COVID was something that was unprecedented, that we'd never seen before in health care, even from a coding perspective . . . and the system wasn't prepared for it.").) However, the COVID-specific guidance fares no better in terms of providing a clear answer in this case.

Guidance from 2020 provided that the full spectrum of E/M codes were available to providers to be billed for COVID-19 testing (i.e., levels 1 through 5 were available) for in-office and telehealth visits. (Gov't Ex. 919.) Neither coding expert was asked to opine on the circumstances under which each code might be appropriate. The only person who testified about this guidance was the Defendant, who testified that he understood level 4 to apply to the patient encounters based on the relevant guidelines. (Tr. X-167, Elfenbein.)

Guidance from 2020 also provided that "for the duration of the [public health emergency], we will recognize physician and NPP [non-physician provider] use of CPT code 99211 . . . to bill for a COVID-19 symptom and exposure assessment and specimen collection provided by clinical staff incident to their services." (May 8, 2020 Interim Final Rule, Def. Ex. 219; *see also id.* (explaining that "[i]n cases where the specimen is collected during a visit where the face-to-face interaction only involves clinical staff of the billing professional . . . these services are generally reported using CPT code 99211").)[22]

[22] The Government also presented a document from the Maryland Local Health Department Billing Manual. (Gov't Ex. 931.) That document indicated that "[i]n the IFR, CMS clarifies that it will allow the use of CPT code 99211 . . .

The only person who explained what this guidance meant was Miscoe. He testified that Medicare generally does not pay for specimen collection, and this rule permitted the use of the 99211 code for that purpose. (Tr. IX-88–89.) He testified that this code did not apply when a provider was involved, and that the code applied when only "ancillary staff"—such as medical assistants—were involved, but not when a qualified health care practitioner was involved in the patient encounter. (*Id.*; *see also* Tr. IX-48 (Miscoe explaining that the key language in this guidance is the reference to clinical staff).)

The Government suggested at trial that 99211 was the correct code for the DEC visits. (*See, e.g.*, Tr. XI-89–90 (Government's closing argument).) However, this argument is not supported by the evidence presented at trial. For instance, Quindoza testified as follows regarding the 99211 code:

> Q. Did CMS issue guidance on what code could be used for Medicare for assessment and specimen collection for COVID tests?
>
> A. Yes, sir, it did.
>
> . . .
>
> Q. What code did CMS identify for those services?
>
> A. It would be code 99211.

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for COVID-19 assessment and specimen collection by a physician, qualified health care professional, or clinical staff for new or established patients for the duration of the PHE." (*Id.*) The only testimony clarifying this document was from Miscoe, who testified that the "guidance, of course, doesn't control how we evaluate Medicare claims or how we would evaluate CareFirst claims" and that it only applied to "claims subject to the guidance of the Maryland Department of Health." (Tr. IX-55–56.) The following discussion occurred at sidebar regarding this document:

> [Counsel for Defendant]: . . . Now that I've looked more closely at it, first of all, he's not accurately characterizing the CMS. What he is characterizing is the Maryland Local Health Department's billing manual. This is a Medicaid billing manual. It has nothing to do with Medicare or CareFirst.
>
> The Court: Well, you let it in. What do you want me to do about it now? I would have sustained your objection, but you admitted it. So it's a problem for redirect.

(Tr. IX-55.) The Government, apparently recognizing the irrelevance of this document, does not cite to it in its briefing.

> Q. And if we can bring up Government's Exhibit 118.[23] What is the definition of CPT code 99211?
>
> A. All right. It says, may not require the presence of a physician or other qualified health care professional. Usually the presenting problems are minimal. Typically, five minutes are spent performing or supervising these services.
>
> Q. And is this the code that Medicare specified for COVID-19 assessment and specimen collection by a physician, qualified health care professional, or clinical staff for both new and existing patients?
>
> A. Yes.

(Tr. I-102.) Even viewing the evidence in the light most favorable to the Government, this exchange is, at best, confusing. It is at worst misleading. The Government did not use any of the guidance itself—which states that it applies to COVID-19 testing *incident to* a physician's services—in questioning Quindoza. Yet the Government omitted this critical point. Further, on cross-examination, Quindoza admitted that he was unaware of much of the COVID-specific guidance prior to testifying, which included guidance relating to the 99211 code. (*See* Tr. II-32 (Quindoza testifying that he was not aware of Defendant's Exhibit 214, which provided that "[p]hysicians and NPPs [non-physician providers] must use CPT code 99211 to bill for a COVID-19 symptom and exposure assessment and specimen collection provided by clinical staff (such as pharmacists) incident to the physician's or NPP's services."); *see also* Tr. II-45 (Quindoza testifying that he was not aware of Defendant's Exhibit 233, in which CMS and the CDC announced that "payment is available to physicians and health care providers to counsel patients, at the time of [COVID-19] testing, about the importance of self-isolation after they are tested and prior to the onset of symptoms" and that "CMS will use existing [E/M] payment codes to reimburse providers").)

[23] This exhibit is not the guidance relating to 99211, it is a summary document created by Quindoza that provides the CPT codes and definitions.

2. The Evidence Presented at Trial Did Not Establish the Falsity of the Level 4 Coding Beyond a Reasonable Doubt and No Reasonable Juror Could So Conclude

Given the complexity and ambiguity of the CPT Manual and related guidance, the Government was required to provide the jury with evidence that would allow the jury to determine—beyond a reasonable doubt—that the level 4 billing for the charged counts was false. The Government did not meet its burden. The Government introduced very little expert evidence at trial related to the CPT Manual and related guidance, what the terms in the CPT Manual mean, and how they related to the charges in this case. The Government also did not present sufficient lay person evidence to overcome this deficiency.

a. Expert Testimony Did Not Establish Beyond a Reasonable Doubt that the Level 4 Coding was False

In "upcoding" cases such as this one, the Government generally introduces expert testimony regarding the falsity of the coding decisions. *See, e.g.*, *United States v. Sharp*, 400 F. App'x 741, 744 (4th Cir. 2010) ("[The medical coding and billing expert] testified that she reviewed the office visit progress notes maintained by [the defendant] and determined that [the defendant's] billings were not supported by the documentation."); *United States v. Janati*, 237 F. App'x 843, 847 (4th Cir. 2007) ("The government's expert testified at trial that none of the charged visits came 'even close' to warranting the Code 99215 billing level."); *United States v. Martinez*, 588 F.3d 301, 316 (6th Cir. 2009) ("[The Government's expert witness] testified that he reviewed the bills [the defendant] submitted and his patient files . . . and concluded that the billing was 'not appropriate in any fashion' and that the procedures claimed in the billing were 'not medically necessary in any way.'"); *United States v. Canon*, 141 F. App'x 398, 405 (6th Cir. 2005) ("[O]ne of the government's expert witnesses [ ] testified that she had reviewed [the defendant's] patient records for the dates listed in the indictment and that the documentation did not support [his] use

of the 99214-25 billing code on those dates."). In fact, "[m]edical billing and coding experts have been used for this purpose without dispute in the Fourth Circuit." *Sharp*, 400 F. App'x at 747; *see also United States v. Janati*, 374 F.3d 263, 271–72 (4th Cir. 2004) (noting that medical coding experts are used "to determine whether . . . documentation supports . . . billings under [the] CPT").

This makes good sense, as "[t]he ordinary juror is not expected to have knowledge regarding CPT codes[.]" *Counts v. Pollock*, Civ. No. 18-1072-J-39JBT, 2020 WL 5534444, at *3 (M.D. Fla. Aug. 21, 2020); *see also Thompson v. Brisk Transp., LP*, 401 F. App'x 826, 828 (4th Cir. 2010) ("[E]xpert testimony is necessary in cases in which the conclusions to be drawn by the jury depend on the existence of facts which are not common knowledge." (citation and quotations omitted)); *cf. United States v. Offill*, 666 F.3d 168, 175 (4th Cir. 2011) (explaining, in a securities fraud case, that "the specialized nature of the legal regimes involved in this case and the complex concepts . . . , and specific regulatory practices make it a typical case for allowing expert testimony" and that "we find it difficult to imagine how the government could have presented its case against [the defendant] without the assistance of expert testimony to explain the intricate regulatory landscape and how securities practitioners function within it"). Of course, there are instances where the falsity of the billing is so obvious that expert testimony will not be particularly helpful to a jury. For instance, in *United States v. Hartz*, 64 F.3d 660 (Table) (4th Cir. 1995), the court concluded that no expert testimony was necessary where the defendant used a CPT code for "individual medical psychotherapy by a physician" where the Government presented evidence that no physician was involved and where the services were not "medical psychotherapy" but were "essentially explorations into the realm of psychic phenomena." This is not such a case.

The Government argues that it was not required to offer "expert testimony that the Defendant's Level 4 billings for the charged patient encounters were false" and that it "did not

need an expert audit to show that Level 4 was incorrect." (ECF No. 85 at 7.) However, here, not only did the Government present no expert testimony regarding the five counts of the Indictment and the propriety of the coding associated with those visits, but the Government also did not present any expert testimony clarifying the meaning of any of the terms in the CPT Manual and related guidance. The Government argues that it did not need to present expert testimony and that it "adduced evidence that the Level 4 billing was false based on what actually occurred during these patient encounters." (ECF No. 85 at 7.) However, without understanding what the CPT Manual required, the jury did not have a reference point to determine whether "what actually occurred" amounted to a level 4 visit.

In sum, there is no reasonable way to construe the expert testimony presented in this case as establishing falsity beyond a reasonable doubt.

i. Stephen Quindoza and Michael Miscoe

The Government's only expert, Stephen Quindoza, was qualified as an expert in "Medicare; Medicare processes, rules, and regulations, including enrollment, participation, the processing of claims, coverage, and procedural and diagnostic coding." (Tr. I-62.) He did not testify regarding whether any of the charged counts were appropriately coded as level 4 visits. During his testimony, he did not provide any color beyond the text in the CPT Manual itself regarding level 4 visits, moderate level medical decision making, or undiagnosed new problems with uncertain prognosis. (*See, e.g.*, Tr. I-99 (Quindoza reading the definitions of 99204/99214 visits as they appear in the CPT Manual).) He also did not testify regarding the meaning of "undiagnosed new problem with uncertain prognosis" or whether presenting for a COVID-19 test could qualify as such. As discussed above, Quindoza was similarly lacking with respect to COVID-specific guidance, as he was generally unaware of the guidance on which he was

questioned. Quindoza failed to offer testimony from which a reasonable juror could conclude that the level 4 designation for the visits was false. The Government appears to concede this point, as it does not cite to Quindoza's testimony other than to establish a minor point regarding the ownership of DEC.[24]

Michael Miscoe, the Defendant's expert who was qualified as an expert "in the fields of medical coding, evaluation and management coding, diagnostic coding, documentation of medical services and medical records" (Tr. VIII-133), testified that each of the five charged counts qualified as level 4 visits. (Tr. VII-200, Tr. IX-3, Tr. IX-7.) In addition to testifying regarding the specific counts, he also testified regarding the meaning of various terms in the CPT Manual[25] and, as discussed above, in the COVID-specific guidance.

Miscoe testified that presenting for a COVID-19 test was an "undiagnosed problem with uncertain prognosis." He explained that this was so given the guidance to use the Z20.828 and the Z20.822 diagnosis codes in connection with COVID-19 testing and given the nature of the COVID-19 virus. (Tr. VIII-173–74 (explaining that the instructions were that there was a presumption that the patient had been exposed to COVID-19, given the instructions regarding the diagnosis codes).) He explained that the problem is "undiagnosed"—given that there is not yet a diagnosis—and that "the prognosis for someone who potentially has COVID" was not "well-defined." (Tr. VIII-180.) He noted that the disease "affected people differently" and that "at that time, no one knew what was going to happen with that patient, and the[re] were many, many

[24] The Court expressed concern during trial regarding Quindoza's testimony, explaining that his testimony appeared to undermine "the underlying . . . legal foundation for it all." (Tr. II-29.)

[25] Although the Court does not focus on the 2020 CPT Manual here, given that the 2021 CPT Manual provided the relevant guidance for the counts in the Indictment, Miscoe also provided detailed testimony regarding the various terms in the 2020 CPT Manual. (*See* Tr. VIII-145–69 (Miscoe explaining terms associated with defining the level of "history" and "examination" and how they are applied).)

factors that could influence that determination." (Tr. VIII-180.) He also testified that "we don't know how the condition is going to react to treatment" and that "in 2020 and 2021, there really weren't approved treatments for COVID." (Tr. IX-44.) Miscoe also testified that he believed that "the likelihood of morbidity . . . is a reflection of the fact of how the Government reacted to this pandemic in terms of quarantining, Hazmat suits for providers, and so forth." (Tr. IX-70.)

The CPT Manual includes other types of potential problems, which are associated with lower CPT codes: a self-limited or minor problem; stable, chronic illness; and acute, uncomplicated illness or injury. "1 self-limited or minor problem" is associated with level 2 decision making, while "2 or more self-limited or minor problems"; "1 stable, chronic illness"; and "1 acute, uncomplicated illness or injury" are associated with level 3 decision making.[26] (2021 CPT Manual at 16.) Miscoe testified that none of these descriptions could be applied to COVID-19 testing encounters. He explained that "the idea that it's a self-limited or minor problem is somewhat absurd because otherwise . . . we wouldn't have had a Public Health Emergency over

[26] These problems are also defined in the 2021 CPT Manual:

> Self-limited or minor problem: A problem that runs a definite and prescribed course, is transient in nature, and is not likely to permanently alter health status.
>
> Stable, chronic illness: A problem with an expected duration of at least one year or until the death of the patient. For the purpose of defining chronicity, conditions are treated as chronic whether or not stage or severity changes (eg, uncontrolled diabetes and controlled diabetes are a single chronic condition) . . . Examples may include well-controlled hypertension, noninsulin-dependent diabetes, cataract, or benign prostatic hyperplasia.
>
> Acute, uncomplicated illness or injury: A recent or new short-term problem with low risk of morbidity for which treatment is considered. There is little to no risk of mortality with treatment, and full recovery without functional impairment is expected. A problem that is normally self-limited or minor but is not resolving consistent with a definite and prescribed course is an acute, uncomplicated illness. Examples may include cystitis, allergic rhinitis, or a simple sprain.

(2021 CPT Manual at 13.) To the extent the Government urges a "common sense" reading of the CPT Manual, it is not clear how COVID-19 could qualify as any of these conditions. Just as the Government urges that COVID-19 is not like a lump in the breast, it could also be said that COVID-19—particularly in 2020 and 2021—is not like well-controlled hypertension, a cataract, or a sprain. It also stretches logic to suggest that COVID-19 could be described as "not likely to permanently alter health status."

it." (Tr. VIII-179.) He also testified that "stable, chronic" and "acute, uncomplicated" refer to how long a patient has had a condition and that these descriptions could not apply to a COVID-19 testing encounter because "we don't even have a diagnosis yet." (Tr. VIII-179–80.)

The only other person to testify regarding the meaning of an undiagnosed new problem with uncertain prognosis was Sinagra, who testified that exposure to COVID-19 "could be" an undiagnosed new problem with uncertain prognosis, or that it could be straightforward. (Tr. V-171–72.)[27]

The jury clearly did not credit Miscoe's testimony, and they were, of course, entitled to do so. However, in this case, there was no testimony that the jury could credit over Miscoe's with respect to the definitions in the CPT Manual and how they are applied to COVID-19 testing encounters. The Government did not present testimony with respect to the definition of an "undiagnosed new problem with uncertain prognosis," whether presenting for a COVID-19 test in 2020 or 2021 qualified as such a problem, or whether two COVID-19 tests and reviewing the results of those tests met the requisite threshold. Here, the Court is not weighing the testimony of two different experts—something the Court is not permitted to do in ascertaining the sufficiency of the evidence. Rather, the Government provided no expert testimony regarding these highly relevant issues at all. *Cf. United States v. Persaud*, 866 F.3d 371, 383 (6th Cir. 2017) (rejecting a sufficiency challenge to an upcoding scheme where the defendant "attack[ed] only the methodology of the government's expert witness, arguing that she relied upon incomplete information," explaining that "[t]he jury had ample opportunity to hear from both parties' expert

[27] This testimony is somewhat inexact, because "straightforward" is not a type of problem, it is a type of medical decision making. Nevertheless, "straightforward" decision making involves "1 self-limited or minor problem." A "self-limited or minor problem" is defined as "[a] problem that runs a definite and prescribed course, is transient in nature, and is not likely to permanently alter health status." (2021 CPT Manual at 13.)

witnesses during trial" and that they favored one expert over another "does not undermine the evidentiary basis of the jury's verdict").

The Government argues that Miscoe's testimony "has no value" because the medical records upon which he relies are inaccurate, vague, and misleading. (ECF No. 85 at 11–12.) First, viewing the evidence in the light most favorable to the Government and assuming that the records are misleading in the ways the Government suggests, this had little impact on Miscoe's conclusions. These inaccuracies on their own do not prove the Government's theory of fraud. Errors or inaccuracies in the medical records notwithstanding, there is no real dispute that the patients presented to get COVID-19 tests, they received two tests, and the result of one test was reviewed on the date of the encounter. Miscoe concluded that each of the charged encounters should be billed at a level 4 because presenting for a COVID-19 test is considered an "undiagnosed new problem with uncertain prognosis" and because each patient received two tests and the results of at least one test was reviewed on the day of the encounter. The evidence at trial established that the patients each met these criteria, despite any inaccuracies in the records. Second, Miscoe did not only opine on the specific counts in the case, he also provided definitions and explanations of ambiguous and complicated concepts. Finally, and critically, the Defendant bears no burden of proof in a criminal case. The Defendant was not required to present an expert witness at all, and had Miscoe not testified, the Court would still conclude that the Government had not proven its case.

Based on the CPT Manual and the expert evidence presented in connection with CPT coding, not only is there insufficient evidence to prove that the Defendant's reading was unreasonable, but there was evidence that affirmatively supports Defendant's understanding of the coding requirements. There is simply not sufficient evidence that the Defendant's reading of the

CPT Manual was not in compliance with the coding requirements such that a reasonable jury could find falsity beyond a reasonable doubt.

ii. Hugh Hill

The evidence at trial showed that DEC providers sometimes saw more than 100 patients in a day. Dr. Hill testified that he "doubt[ed] if they were seeing that many personally" and that "the statistics on this say that a small percentage of providers can see 50 to 60 patients in a day, depending on the circumstances." (Tr. VIII-106.) The Government points to this testimony and argues that "Dr. Hill's testimony, without more, shows that the Defendant's Level 4 billing scheme was false." (ECF No. 85 at 8–9.) This argument misses the mark. Dr. Hill did not provide any testimony at all about E/M coding, and his testimony does not speak to the falsity of the level 4 billing. The alleged scheme in this case was not that providers were not seeing the patients, it was that the level 4 billing did not describe those encounters.

iii. Government's Arguments

The Government's arguments are largely untethered from the language in the CPT Manual. The Government argues that "[t]he contention that every individual who received a COVID-19 test always qualified for a Level 4 evaluation and management visit does not pass the smell test." (ECF No. 85 at 27.) However, when the foundation for a conviction is a complex set of coding rules, the "smell test" does not cut it.

The *only* argument the Government makes that is tied to the language in the CPT Manual is that presenting for a COVID-19 test is not an "undiagnosed new problem with uncertain prognosis" because it is not like a "lump in [the] breast." (ECF No. 85 at 10.) The Government presented no evidence at all on this point. In fact, the only evidence regarding whether presenting for a COVID-19 test is like having a lump in the breast was from Miscoe, who testified that having

a lump in the breast is indeed comparable to an undiagnosed COVID patient because "[i]t's an undiagnosed new problem that you don't know what's going to happen with it, in terms of the risk of compromise of health or bodily function, without treatment." (Tr. IX-69.) The jury was not required to believe Miscoe, but there was no countervailing evidence for the jury to consider on this point.

The Government also points to the emails in which the Defendant explains that "the patients are all here for one reason….simple and straightforward-to get tested" (Gov't Ex. 646) and that "[w]e are not there to solve complex medical issues, etc… Just to test them." (Gov't Ex. 647.) However, the terms "straightforward" and "complex" for purposes of determining the appropriate code for a patient encounter have specific definitions, as discussed above. They do not retain their conventional, plain-English meaning in this context. While these emails may be highly relevant to the Defendant's intent, they are not proof of the falsity of the level 4 billing.

The Court also pauses here to discuss the Government's continual references to time, both in briefing and at trial. (*See, e.g.*, Tr. XI-92 (Government arguing in closing that "you don't need to be a Certified Professional Coder to figure this out . . . . A five-minute or less drive-through COVID screening is not even close to the moderate complexity, typically 45-minute office visits Dr. Elfenbein was billing").) The Government suggests that the number of patients and the time it took to see each patient indicates that the visits were not level 4 visits. However, there is no evidence that providers were to consider patient volume or time when utilizing the medical decision making chart to code visits. Further, the CPT Manual does not provide any minimum time for coding purposes and, in 2021, removed the reference to typical times altogether. The Government's expert testified that time was not a factor used to select the coding level.[28] (Tr. I-

[28] At one point, Quindoza expressed some incredulity that a provider could conduct the requisite history and exam in five minutes. (Tr. I-200–01.) However, the 2021 CPT Manual expressly provides that "the extent of history and

205, Quindoza.) The Government itself conceded this point during trial. (*See* Tr. I-27 (Government opening argument explaining that this trial is "not about whether a level 4 office visit was required to take a certain amount of time").)

In short, to sustain its burden to prove each element of the crime beyond a reasonable doubt, the Government could not rely solely on the terms as they appear in the CPT Manual and then urge the jury to use its common sense. Rather, the Government had to present the jury with evidence to help guide the jury's application of the CPT Manual and its codes to the Defendant's conduct. As discussed above, the expert testimony at trial did not provide sufficient evidence from which a juror could conclude beyond a reasonable doubt that the level 4 billing was false.

b. Lay Testimony Did Not Establish Beyond a Reasonable Doubt that the Level 4 Coding was False

Without expert testimony regarding the terms in the CPT Manual and how it applies to the facts of this case, the Government may still have been able to salvage its case. However, the lay testimony in this case also did not provide a basis upon which a reasonable juror could conclude beyond a reasonable doubt that the level 4 coding was false.

As an initial matter, the Court addresses the Government's contention that certain lay witnesses were in fact testifying as "hybrid" witnesses. Apparently recognizing the weakness in its expert witness testimony, the Government argues in its briefing that two of its witnesses—Raymond and Sinagra—and two of the Defendant's witnesses—Carroll and Silva—testified as "hybrid witnesses." (ECF No. 85 at 13.) The Government cannot bypass the court's critical gatekeeping function with respect to expert testimony. These witnesses were not hybrid witnesses, and the Government cannot now recast them as such. In addition, to properly admit dual-role

physical examination is not an element in selection of the level of office or other outpatient codes." (2021 CPT Manual at 12.) Nevertheless, Quindoza later testified that time was not a factor.

testimony, the Court is required to "implement[] adequate safeguards to prevent juror confusion or jurors giving undue weight to the lay testimony." *United States v. Baptiste*, 596 F.3d 214, 224 (4th Cir. 2010). Because these witnesses were not identified as dual-role witnesses during the course of trial, the Court did not erect safeguards with respect to their testimony.

i. Sinagra and the CareFirst Audit

Sinagra—a CareFirst auditor who testified as a lay witness but who the Government now seeks to recast as a hybrid expert[29] —testified about two CareFirst audits. Her testimony and the CareFirst audits did not provide sufficient evidence that the level 4 billing was false.

The first audit, issued on April 28, 2021, concluded that the COVID-19 testing visits should be coded as level 3 visits. (Gov't Ex. 501.) Sinagra testified that there were records missing when CareFirst conducted this audit. (Tr. V-32 (Sinagra testifying that she did not know if the auditor requested the missing pages at any point); Tr. V-96 (Sinagra estimating that 40 percent of the pages were missing).) And she agreed that it was a "fair assessment" to say that she did not know whether a review of the complete records would have supported DEC's level 4 coding. (Tr. V-127–28.) The second audit, issued on March 8, 2022, concluded that the visits should be coded as level 2 visits. (Gov't Ex. 502.) Sinagra agreed that it would be "fair to say that auditors don't necessarily make the same findings as to specific claims" and that "a one-level difference . . . would not necessarily be out of the ordinary." (Tr. V-149–50.) She did not otherwise explain the one-level coding difference between the two audits.

Even when the Court views this evidence in the light most favorable to the Government, this is not sufficient evidence from which a reasonable jury could conclude beyond a reasonable

[29] The Government's argument that Sinagra testified as a hybrid witness is particularly troubling. At trial, the Government objected to questions during her cross-examination, explaining that "[t]his witness is not being offered as an expert" and that she was only "talking about what CareFirst did[.]" (Tr. V-77.)

doubt that the level 4 billing was false. The CareFirst auditors first concluded that the visits should have been coded as level 3 visits based on incomplete records, Sinagra did not know whether complete records would support a level 4, and a later audit concluded that they should have been coded as level 2 visits. Most critically, Sinagra agreed that a one-level difference between coding in audits would not be unusual.

In addition, Sinagra's testimony was limited to the CareFirst audits, and it is not clear the extent to which the results of the CareFirst audit can be extrapolated to establish the falsity of any of the Medicare counts. Sinagra's testimony was unclear as to whether the CareFirst requirements were identical to the Medicare requirements. For instance, she explained that CareFirst followed CMS guidance on documentation of the medical record "as well as our own medical policy that is available to all of our providers through the CareFirst.com website, as well as within the provider contract." (Tr. V-67.) In testifying about the first audit, she explained that the general finding of the first audit was that DEC was "not adhering to medical policy in the provider contract[.]" (Tr. V-35.)[30]

[30] There are other discrepancies between CareFirst's standards and Medicare standards that were never clarified at trial. For instance, the second audit cites to CareFirst's Medical Record Documentation Standards, which provide that "[t]he record is expected to include such information as a history, examination, diagnosis, treatment, or treatment and follow up care as outlined in Provider Guidelines." (Gov't Ex. 502.) Further, the guidelines appended to the audit acknowledge the 2021 change to CPT coding and note that "CMS 1995 and 1997 Documentation Guidelines continue to remain as a clinical reference for E/M Services. Providers should reference available guidelines when documenting E/M services to determine the required medical record documentation appropriate to the E/M service provided." (Def. Ex. 255 at 8.) It further notes that providers should "[b]ase the level of E/M service reported on the extent of the patient's history and/or examination and/or the complexity of the medical decision-making required, all of which must be supported in the patient's medical record." (*Id.*)

However, as discussed above, relevant guidance removed the requirement for documenting history and examination for virtual visits and, in 2021, history and examination no longer drove code selection. Further, the witnesses uniformly testified that the 1995 and 1997 guidelines no longer applied to claims for dates of service after January 1, 2021. (Tr. I-165, Quindoza; Tr. V-137, Sinagra.)

Finally, it is not entirely clear the extent to which CareFirst followed certain of the COVID-specific guidance. (*See* Tr. V-75 (Sinagra testifying as follows with respect to Def. Ex. 214, COVID-related coding guidance: "Q. Okay. Now, is it your testimony, then, that CareFirst was not paying for those services? A. We do pay for those services, but this particular press release is regarding CMS's guidance regarding their in-network providers. Q. It's also CDC's

ii. DEC Employees

Raymond and Wrona both testified that they believed the visits should be coded as level 3 visits. Critically, both of these employees left DEC in 2020, before the 2021 coding changes and before Earleigh Heights opened. (*See, e.g.*, Tr. IV-37, 42 (Raymond testifying that, when she worked at DEC, they "were working under the three key factors model" and that there was "a change in 2021, but [she] wasn't there for that"); Tr. IV-89 (Raymond testifying that 2021 guidance provided that the medical decision making was the relevant criteria, and history and examination were no longer criteria).) Neither witness's testimony establishes that the 2021 level 4 coding was false.

Raymond's concerns related to the level of documentation with respect to the history and exam, not medical decision making. For instance, she explained that she raised concerns with the Defendant regarding the billing levels and that "[i]n order for us to be billing those high-level office visits, [she] need[ed] to have a complete patient history entered, and it was not entered." (Tr. IV-7.) She also testified that she was "okay" with billing COVID-related visits at level 4 and 5 "[i]f [she] had the documentation to support it in the history and the exam." (Tr. IV-45; *see also* Tr. IV-90 (Raymond testifying that her concern was the "consistent pattern of level 4s and 5s being billed but without the appropriate documentation level to support it"); Tr. IV-96 (Raymond testifying that the "physical exam rated at a 3").) However, the 2021 CPT Manual provided that coding was based on medical decision making (when it was not based on time) and explained that "the extent of history and physical examination is not an element in selection of the level of office or other outpatient codes." (2021 CPT Manual at 12.) In addition, for visits that were conducted

guidance, correct? A. Yes. Q. Okay. And did you follow this guidance? A. We followed guidance as it appears in our medical policies within CareFirst, as well as CMS. Q. Is that a yes? A. Yes.").)

virtually (such as the Earleigh Heights visits), the April 6, 2020 Interim Final Rule provided that there were no documentation requirements for history or physical exam for telehealth visits. (Def. Ex. 218.)

Needle testified that she believed that the visits should be coded as level 3 visits and that "[h]istorically, that was [her] feeling, but [she] had never lived through a pandemic before." (Tr. IV-207.) Needle testified that she "didn't feel that an asymptomatic patient warranted a level 4" and that she "felt like it was a higher code." (Tr. IV-139, 142.) She also testified that she had "never practiced in a pandemic before" and therefore did not know what the appropriate code was and looked to the Defendant for guidance. (Tr. IV-151.) She also testified that, prior to working at DEC, she did not have any coding experience and she was not familiar with E/M codes. (Tr. IV-134; *see also* Tr. IV-156 ("I graduated a long time ago . . . I still wasn't sure that the coding we were told to code was correct. Again, it was a pandemic, and I was told these were pandemic codes because of a deadly virus").) This testimony likewise does not prove that the level 4 coding was false. It is not grounded in the CPT Manual or related guidance, and, as Needle explained, she was not familiar with coding.

The Government argues that Silva and Carroll's testimony also supports the jury's conclusion. As noted above, neither of these witnesses testified as an expert, but the Government now seeks to recast them as hybrid witnesses. The Government then selectively quotes from the testimony.

For instance, the Government points to the following exchange as proof of the falsity of the level 4 billing:

> Q. And why did the patient come to FirstCall?
> A. Needs a test for work.
> Q. How'd you code the office visit?
> A. 99214.

Q. And is the care plan identical to the last care plan we just saw?
A. Yes.
Q. Do you think that's a level 4 decision making, Mr. Carroll?
A. No.
Q. This visit should not have been a level 4.
A. No.

(Tr. VIII-43, Carroll.) However, the Government omits the next part of the exchange, where Carroll explains that he coded the visit that way, not because the Defendant told him to, but because "[a]t the time [he] thought it was the appropriate coding." (Tr. VIII-44.) Carroll did not explain why his understanding was different now.

Carroll testified that an email from the Defendant describing a five-minute encounter did not describe a level 4 encounter. (Tr. VIII-41.) However, Carroll testified that he believed level 4 was the appropriate code at the time because "[he] felt that the level 4 was moderate level, plus review of the test, history, review of systems, and physical exam." (Tr. VIII-22.) He explained that he had reviewed the guidance regarding coding during COVID-19. (Tr. VIII-22–23.)

The Government argues that Silva "testified that when she saw patients in-person at the FedEx Field location, she coded the office visit as a level 3: 'if the patient circumstance was extremely straightforward, such as they simply needed a test for travel or work and were having absolutely no symptoms, I didn't need to take time consulting with them, helping them with any concerns, then I might code those as a level 3.'" (ECF No. 85 (quoting Tr. IX-110).) She also testified that she "may have billed more 3s at Earleigh Heights given that my exam was more limited." (Tr. IX-110.)[31] However, the Government again selectively quotes testimony. Before providing that answer, she explained that "[a]t any location [she] would use a level 3 rarely." (Tr.

[31] No testimony at trial squared this testimony with the 2021 CPT Manual's directive that "the extent of history and physical examination is not an element in selection of the level of office or other outpatient codes." (2021 CPT Manual at 12.)

IX-109.) Silva testified that, in general, she believed level 4 was appropriate given "the complexity of the decision making, the thoroughness of the physical exam, and the history taking." (Tr. IX-107.) She did not code them as level 4s because the Defendant told her to. (*Id.*)

At an absolute maximum, Carroll and Silva's testimony reflects that, under certain limited circumstances, a level 4 was not appropriate. None of the charged counts relate to those circumstances—as discussed in more detail below, each of the charged counts either had a known COVID-19 exposure and/or had symptoms. Further, both Carroll and Silva explained that they were not pressured to code at a particular level. (Tr. VIII-23, Carroll; Tr. IX-109, Silva.)

Finally, the Government also points to testimony from David Turner. (ECF No. 85 at 16.) Turner testified that the coding practices of another provider in Centennial Medical Group "were more conservative." (Tr. II-181.) However, critically, the Government never established precisely what type of services were provided by the other provider.[32] It is therefore not clear at all what relevance this testimony has. The Government misstated this testimony later in the trial when it cross-examined the Defendant. The Government asked whether the Defendant remembered Turner testifying that "the other practice that Mr. Ferguson managed that was eight to ten times the size of yours *didn't bill their COVID testing the same way*[.]" (Tr. X-159 (emphasis added).) Viewing this evidence in the light most favorable to the Government and assuming that Turner was referring to COVID testing, there was no evidence presented regarding what these COVID testing encounters entailed (i.e., Did they include two tests? When were test results reviewed? Did patients see providers, or only clinical staff?) and this is insufficient to prove that the Defendant's interpretation of the coding guidance was not reasonable.

[32] Without any citation to the record, the Government states in its briefing that "Dr. Dua's practice also provided COVID-19 testing services in Maryland." (ECF No. 85.)

The foregoing evidence, like the expert testimony, does not prove beyond a reasonable doubt that billing patients at a level 4 was false. Nor does it provide sufficient evidence from which a jury could conclude that the Defendant's interpretation of the CPT Manual was not reasonable.

3. Individual Counts

The Court now comes to the five individual counts in this case, each of which represents an alleged execution of the Defendant's allegedly fraudulent scheme. As the Court instructed the jury, they could "not find the defendant guilty of a count . . . unless [the jury found that] the Government has proved beyond a reasonable doubt that the claim charged in that count . . . was false or fraudulent as to a material fact or matter." (Tr. XI-127 (Jury Instruction 39).)

Each of the visits occurred in 2021. Thus, the code selection for each visit could be based either on time or medical decision making. The code selection in these visits was not based on time. Further, the level of history and examination did not drive code selection in 2021 (*see* 2021 CPT Manual at 12), and, because each of the visits was a virtual visit, there were no documentation requirements with respect to the history and examination. (*See* April 6, 2020 Interim Final Rule, Def. Ex. 218 ("remov[ing] any requirements regarding documentation of history and/or physical exam in the medical record" for the duration of the COVID-19 public health emergency).)

As discussed at length above, to find the Defendant guilty, the Government was required to prove beyond a reasonable doubt that each of these visits did not involve "moderate" level medical decision making, as that term is defined in the CPT Manual. In other words, the Government was required to prove beyond a reasonable doubt that each of the patients did not have an "undiagnosed new problem with uncertain prognosis" or that each patient did not receive

two unique tests and the results of one of the tests on the date of the encounter. The Government did not carry its burden.

a. Counts 2–5 (S.T., J.J., D.M., and W.R.)

With respect to Counts 2–5, the evidence at trial established each patient presented for a COVID-19 test due to either an exposure or symptoms, that they briefly saw a provider, that they received a rapid test and a PCR test, and that the results of the rapid test were received on the date of the encounter.

S.T. came to DEC to be tested for COVID-19 due to an exposure from her children's daycare. (Tr. IV-99.) S.T. briefly saw a provider, who asked her questions regarding why she was there and whether she had symptoms. (Tr. IV-101.) She explained that she and her three children saw the provider for about ten minutes. (Tr. IV-102.) S.T. received a rapid test and a PCR test. (Tr. IV-102–03.) The results from the rapid test were received on the date of the encounter. (Gov't Ex. 408.)

J.J. testified that she came to DEC to be tested for COVID-19 due to a COVID-19 exposure at work. (Tr. V-8.) Upon being shown a handwritten form that indicated that her reason for testing was "symptoms" and that she had fatigue, nasal congestion, headache, and sweats, she agreed that the document had her handwriting. (Tr. V-9; *see* Gov't Ex. 405.) J.J. saw a provider for about "two minutes" and the provider asked questions about her symptoms. (Tr. V-6.) She received a rapid test and a PCR test. (Gov't Ex. 405.) The results from her rapid test were reviewed the same day as her visit. (Gov't Ex. 405.)

D.M. testified that she received a COVID-19 test at DEC to visit a family member. (Tr. III-69.) She also agreed that her signature was at the bottom of a page on which "I have been exposed" was circled. (Tr. III-74.) She testified that she saw a provider for about five minutes.

(Tr. III-69.) She received a rapid test and a PCR test. (Tr. III-70; Gov't Ex. 404.) The results from her rapid test were reviewed the same day as her visit. (Tr. III-71; Gov't Ex. 404.)

W.R. received a COVID-19 test at DEC because he had been exposed to COVID-19. (Tr. IV-107.) He briefly saw a provider for about five minutes. (Tr. IV-108.) He received a rapid test and a PCR test. (Gov't Ex. 407.) The results from his rapid test were reviewed the same day as his visit. (*Id.*)

As discussed above, the Government did not carry its burden to prove that these visits did not involve moderate level medical decision making, as that term is defined in the CPT Manual. Each visit involved interaction with a provider, including discussion with the provider about symptoms and the reason for testing. Specifically, the Government did not carry its burden to prove either that (1) presenting for a COVID-19 test—here, for individuals that all reported a COVID-19 exposure and some who reported symptoms—was not an undiagnosed new problem with uncertain prognosis or that (2) getting a rapid test and a PCR test and the results of the rapid test did not meet the threshold required for moderate level medical decision making.

b. Count 1 (A.H.)

With respect to Count 1, A.H. testified that she did not see a provider and that if there was a monitor, she did not see it. (Tr. II-109–10.) The evidence otherwise reflects that she had an encounter similar to that of the other patients discussed above. She was tested for COVID-19 because her husband was coming home from surgery. (Gov't Ex. 403 (noting "husband coming" as the reason for testing and that she also had a sore throat).) She received a PCR and a rapid test, and the results of the rapid test were reviewed on the date of the encounter. (Tr. II-106; Gov't Ex. 403.)

The medical records reflect that she *did* see a provider, but—viewing the evidence the light most favorable to the Government—her testimony may suffice to show that she did not see a provider. If so, the visit would not be a level 4 visit, because a provider visit is required for the level 4 code. Nevertheless, assuming she did not see a provider, that is simply *not an execution of the scheme the Government sought to prove*. The Government did not allege or present evidence that provider visits were not happening; instead, it provided evidence that the provider visits were brief and alleged that the visits did not rise to level 4 visits. There is no evidence at all that the Defendant directed providers to bill for encounters that did not occur. To the extent that the provider in this case billed for a patient visit at which she was not present, there is no evidence that such action was at the direction of the Defendant.

4. Summary

The Court does not take lightly the fact that a jury heard the evidence in this case and found the Defendant guilty. However, the ability of a court to entertain a Rule 29 motion "serves [] to highlight the traditional understanding in our system that the application of the beyond-a-reasonable-doubt standard to the evidence is not irretrievably committed to jury discretion." *Jackson v. Virginia*, 443 U.S. 307, 318 n.10 (1979).

The overarching issue in this case is the inherent slack in the medical billing system as it relates to the E/M coding relevant to this case. This purposeful imprecision affords medical providers the flexibility to code across a variety of situations, and that is apparently useful in the medical context. However, this imprecision does not necessarily integrate well with the clear notice and due process guarantees of our criminal law. Here, where the relevant CPT codes and related definitions are ambiguous and subject to multiple interpretations, problems clearly arise. As the Second Circuit has explained:

> We are extremely mindful that Medicare and Medicaid fraud constitute a great drain on a limited source of social funding . . . Those who perpetrate such fraud deserve relentless prosecution and severe punishment, and nothing in our opinion should be read as allowing such despicable individuals to hide behind the ambiguities of bureaucratic regulations. However, neither can we allow the government to ambush a defendant with that same ambiguity.

United States v. Siddiqi, 959 F.2d 1167, 1174 (2d Cir. 1992) (citations omitted). The referenced imprecision, of course, does not preclude an 18 U.S.C. § 1347 conviction based on E/M coding, and the Court does not suggest that ambiguous CPT codes are necessarily fatal to a conviction under this statute. Fraudsters often take advantage of ambiguous circumstances to perpetrate their schemes, and the Court fully appreciates that aspects of the Defendant's purported scheme were unsavory.

However, "the fraud statutes do not cover all behavior which strays from the ideal" and "not all conduct that strikes a court as a sharp dealing or unethical conduct is a scheme or artifice to defraud." *United States v. Colton*, 231 F.3d 890, 901 (4th Cir. 2000) (citations omitted). The Government's contention that the CPT Manual is written in English and that the Defendant's coding did not comport with common sense is too simplistic for criminal liability to attach. The Court appreciates that billing very short COVID-19 testing visits under the second-highest complexity E/M code, in some ways, does not comport with common sense. However, to the extent there is an incongruity between coding outcomes and common sense, the fault lies with the drafters of the CPT Manual and related guidance.[33] The CPT Manual and the accompanying guidance are imperfect tools, and, as this case reflected, they were particularly imperfect in the context of a pandemic.

[33] Common sense may well dictate that a provider who effectively bills $354.22 (Tr. II-78, Quindoza), for a five-minute encounter (Tr. III-69, D.M.) is cheating . . . , but it is not a crime if the Government has authorized him to do it!

The CPT Manual very specifically defined and then utilized various terms that did not retain their plain English meaning, and the Government did not present evidence that would allow a reasonable jury to conclude beyond a reasonable doubt that the Defendant's coding decisions were not within a fair reading of the coding guidelines.

In concluding that the evidence was insufficient to sustain a conviction in this case, the Court does not place insurmountable evidentiary burdens on the Government. It is not impossible for the Government to win convictions in fraudulent coding (or, "upcoding") cases. But in this instance, the Government clearly failed. The Government presented no helpful expert testimony on the critical questions in this case, and the lay testimony it presented fared no better. The "common sense" conclusions the Government asks the jury (and now the Court) to draw amount to speculation, and the Court cannot allow a verdict to stand when it is based on speculation masked as common sense.

In some cases, it will be enough to point to the plain language of the relevant guidance. Take, for example, the *Hartz*[34] case discussed above, in which a jury reasonably found that a defendant's statements were false when she billed for "individual medical psychotherapy by a physician" when she (1) was not a physician, and (2) did not perform medical psychotherapy, but rather performed "explorations into the realm of psychic phenomena." *United States v. Hartz*, 64 F.3d 660 (Table) (4th Cir. 1995).

In other cases, where there are ambiguous terms of art or guidance, more is required. For instance, in *Janati*, the Fourth Circuit sustained a conviction in a case where "selecting the proper billing code for a given visit required some judgment" but "the government's expert reiterated that

[34] That case involved 18 U.S.C. § 1341, a different fraud statute. That statute is similar to the healthcare fraud statute in that it also requires proof of "any scheme or artifice to defraud, or for obtaining money or property by means of false or fraudulent pretenses, representations, or promises[.]"

the visits that she examined were '[n]ot even close' to being properly classified at the Code 99215 level." *United States v. Janati*, 237 F. App'x 843, 845 (4th Cir. 2007); *see also United States v. Sharp*, 400 F. App'x 741, 744 (4th Cir. 2010) ("[The medical coding and billing expert] testified that she reviewed the office visit progress notes maintained by [the defendant] and determined that [the defendant's] billings were not supported by the documentation."). The Government sails in shallow waters when it prosecutes a case of this type; these cases require careful navigation.

One might hope that providers would apply a "common sense" approach when coding, and not take advantage of laxities afforded by the CPT Manual to fill their pockets. However, in this context, it is not a criminal offense to take advantage of loose definitions or an explicit loophole any more than is it to do so when citizens prepare their tax returns. Citizens, including healthcare providers, cannot be held to criminal account for doing only what a technical regulation is reasonably read to permit, even if to do so would seem to benefit them excessively.

To succeed in the prosecution of this case, the Government was required to first prove falsity. Here, the CPT Manual and the COVID-related resources arguably authorized level 4 coding in these circumstances, and certainly there is not proof beyond a reasonable doubt that they did not. From the evidence presented, the Defendant's interpretation of the relevant guidance was a reasonable—if aggressive—reading.

D. Rule 33

Federal Rule of Criminal Procedure 29 provides that "[i]f the court enters a judgment of acquittal after a guilty verdict, the court must also conditionally determine whether any motion for a new trial should be granted if the judgment of acquittal is later vacated or reversed. The court must specify the reasons for that determination." Federal Rule of Criminal Procedure 33 provides that "the court may vacate any judgment and grant a new trial if the interest of justice so requires."

As discussed above, the Court will enter a judgment of acquittal. It will also conditionally grant a new trial, as it finds that the evidence weighs heavily against the verdict. In particular, the Court finds that the weight of the evidence does not support the jury's apparent finding that billing at a level 4 for the charged encounters was false or fraudulent.

1. Weight of the Evidence

The Court is mindful that, in conditionally granting a new trial based on the weight of the evidence, it may not "simply harken[] back to its acquittal analysis" and must provide "further elaboration" beyond the acquittal analysis. *United States v. Rafiekian (Rafiekian I)*, 991 F.3d 529, 549–50 (4th Cir. 2021); *see also United States v. Millender*, 970 F.3d 523, 531 (4th Cir. 2020) (remanding a new trial motion to the district court where the court "offered only a single sentence to explain its decision to order a new trial" which pointed back to the acquittal analysis). For purposes of the below analysis only, the Court will assume that there was sufficient evidence to sustain the convictions on the five counts.

The Court is asked, in assessing a Rule 33 motion, to "evaluate the persuasiveness of the inculpatory evidence in comparison with other evidence[.]" *Rafiekian II*, 68 F.4th at 189. This, the Fourth Circuit has recognized, is "far different" from "simply determining whether there is sufficient evidence to support the verdict, as is required in the judgment-of-acquittal context." *Id.* In the context of a Rule 33 motion, the Court conducts a "global assessment of the evidence" and "weigh[s] whatever evidence it has before it." *Id.* The Court finds that a global assessment of the evidence merits a new trial.

As an initial matter, the Court is permitted, in assessing the weight of the evidence, to assess the credibility of witnesses, and the Court finds that the Government's lead witness and expert, Quindoza, was utterly impeached. As noted above, the Government appears to agree, having not cited to Quindoza for any substantive points in its briefing. Quindoza, who was

qualified as an expert in, *inter alia*, procedural and diagnostic coding, was wholly unaware of coding-related guidance that was highly relevant to this trial. For instance, he was unaware of each piece of guidance that came out during the pandemic about which he was asked. He testified on direct examination that there were no changes to telehealth during the course of the pandemic that reduced the requirements for CPT coding, and that a telehealth visit "still ha[d] to meet all the elements of the CPT codes" from the 2020 CPT Manual. (Tr. I-105–06.) However, of course, the April 6, 2020 Interim Final Rule explained that, for virtual visits, coding was to be based on medical decision making or time, and removed documentation requirements relating to the examination and history. (Def. Ex. 218.) Quindoza conceded during cross-examination that he was incorrect and that he had not reviewed that guidance. In addition, on cross-examination, Quindoza had to retract testimony that he had provided on direct:

> Q. Okay. So when you told the members of the jury earlier that time is a factor in determining the level, that's just not true, is it?
> A. In determining the level?
> Q. Yes, sir.
> A. No, it's not.

(Tr. I-205.) Given these shortcomings in Quindoza's testimony, the Court accords it no weight.

On the other hand, the Court finds Miscoe to be credible. Critically, and as discussed in more detail above, Miscoe's testimony was the only testimony that spoke directly to the requirements in the CPT Manual and related guidance. The Court finds helpful Miscoe's testimony regarding each of the charged counts. More importantly, Miscoe was the only witness to explain what the relevant terms meant, and how they applied in the context of this particular case. For instance, Miscoe testified that COVID-19 qualified as an "undiagnosed new problem with uncertain prognosis" and he explained why that was so, explaining how that conclusion interacted with the ICD-10 guidance regarding diagnosis codes and why the other potential types

of problems (e.g., self-limited or minor problem) did not apply. Miscoe also provided testimony helpful to decoding the COVID-19-specific guidance. For these reasons, the Court accords his testimony great weight.

The Court does not preclude the possibility of proving a case such as this without an expert. However, in the face of such precise and credible expert testimony and in the face of ambiguous guidance, the relative weight of the lay testimony in this case is minimal.

For instance, the Court accords little weight to the testimony of Raymond and Needle, both of whom had left DEC before Earleigh Heights opened and before the 2021 coding changes occurred. The Court accords their testimony that they believed the visits should be coded as level 3 little weight because they did not tie those concerns specifically to the CPT Manual—which provides the very foundation for this case—in the same precise way as Miscoe.

For instance, Needle testified that she did not have significant coding knowledge and that she believed that the visits should be coded as level 3 visits and that "[h]istorically, that was [her] feeling, but [she] had never lived through a pandemic before." (Tr. IV-207.) Raymond's testimony quite clearly related to the documentation of the history and the exam, not of the medical decision making. (*See, e.g.*, Tr. IV-45 (Raymond testifying that she was "okay" with billing COVID-related visits at level 4 and 5 "[i]f [she] had the documentation to support it in the history and the exam").) Therefore, the Court does not accord her testimony weight as it relates to the level of medical decision making and CPT coding in 2021.[35]

[35] The employees who did work at DEC after the coding change who testified regarding the appropriate codes, Silva and Carroll, both testified that they believed a level 4 was generally appropriate and that they did not feel pressure to code in any particular way, and that they sometimes coded lower if necessary. Given that they were employees during the relevant year, the Court accords their testimony more weight than their counterparts.

The Court concludes similarly with respect to Sinagra. Her testimony did not make clear why a one-level coding difference might occur between audits. Without a deeper understanding regarding whether the level 3 designation from the first audit (which was based on incomplete documentation) or the level 2 designation from the second audit is more appropriate, it is difficult to assign any substantial weight to her testimony or the results of the audit.

In short, the Court finds that the inculpatory evidence in this case is more atmospheric[36] while the exculpatory evidence is grounded in the actual guidance that forms the foundation of this case.

It is, of course, impossible to recite herein every possibly relevant piece of evidence or to know exactly what evidence resonated with the jury when it convicted the Defendant on all five charges. The Court is mindful of the critical role that the jury plays and that new trials are to be granted only sparingly. The Court is reminded that the standard for reversing a jury verdict is demanding, and the Court does not overturn a jury verdict lightly. However, the Court, having closely observed the testimony and parsed the evidence in this case, concludes that the evidence weighs so heavily against the verdict that it would be unjust to enter judgment, and that the Defendant is conditionally entitled to a new trial.

2. Evidentiary Issues and Jury Voir Dire

The Defendant raises various evidentiary issues in support of his alternative Motion for a New Trial. (*See* ECF No. 78 at 34–45.) The Defendant also argues that Court erred when it

[36] For instance, the Government presented evidence that the Defendant's income increased considerably in 2021, as compared to prior years. (*See* Gov't Ex. 134 (chart reflecting the Defendant's wages and business and partnership income for 2018–2021).) The Government also presented evidence reflecting the large volume of patients seen by DEC and the amounts billed to and paid by insurers, (*see, e.g.*, Gov't Exs. 103, 104, 105, 111, 112, 113, 138), as well as emails from the Defendant that reflected his desire to treat patients quickly. (*See, e.g.*, Gov't Ex. 647 (December 25, 2020 email in which the Defendant explains that "this is virtual and [the patient] is there for one reason only-to be tested. Goal is to get them seen and out quickly (we want them in and out of the tent in under 5 minutes total).").)

excluded members of the public from the individual voir dire of the jurors. (*Id.* at 45–46.) However, given the Court's conclusion that a new trial is warranted based on the weight of the evidence, the Court declines to address these arguments.[37]

IV. Conclusion

The Court does not take lightly its vacatur of the Defendant's convictions in this case. The Court recognizes the critical role jurors play in our criminal justice system, and the extremely high bar that Rule 29 places upon the Defendant and the Court in overturning a jury's verdict. However, "[i]t has been settled throughout our history that the Constitution protects every criminal defendant against conviction except upon proof beyond a reasonable doubt of every fact necessary to constitute the crime with which he is charged" and "[i]t is equally clear that the Constitution gives a criminal defendant the right to demand that a jury find him guilty of all the elements of the crime with which he is charged." *United States v. Booker*, 543 U.S. 220, 230 (2005). Rule 29 safeguards these rights, and this is the rare case that merits overturning the jury's verdict. The Court—having observed the trial and having carefully parsed the record in this case—concludes that the jury's verdict cannot stand. Thus, an Order will issue vacating the Defendant's convictions, granting the Defendant's Motion for Judgment of Acquittal, and conditionally granting a new trial. A formal Judgment of Acquittal will enter. The Defendant will be discharged.

[37] With respect to the voir dire, the Defendant objects to the Court's closure of the courtroom to the public to conduct the individual voir dire of prospective jurors. First, the Court notes that the Court has followed this practice as a result of the COVID-19 pandemic, and that conducting the individual voir dire in this manner replaced the Court's usual and long-standing practice of questioning individual jurors at the bench. Second, these discussions, while not conducted in public, were all on the record. Finally, the Defendant consented to this arrangement, both at trial and in a pretrial filing. (*See, e.g.*, ECF No. 35 (parties' joint proposed voir dire, which includes instructions to the jury regarding jury selection, including: "Then you will be brought back to the Courtroom, one-by-one, to meet with me and to review the answers that you have provided on your answer sheet. Once you are back in the Courtroom, only court staff, the parties, the lawyers, and I will be present. No one else will hear the answers that you provide."); ECF No. 85-1 (transcript reflecting Defense counsel's agreement with the arrangement).)

DATED this 21 day of December, 2023.

BY THE COURT:

James K. Bredar
Chief Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

UNITED STATES OF AMERICA	*	
v.	*	**CRIMINAL NO. JKB-22-0146**
RON ELFENBEIN,	*	
Defendant.	*	

* * * * * * * * * * * *

ORDER

For the reasons set forth in the foregoing Memorandum, it is ORDERED that:

1. Defendant Ron Elfenbein's Motion for Judgment of Acquittal or, in the Alternative, for a New Trial (ECF No. 78) is GRANTED in part and CONDITIONALLY GRANTED in part. The Motion is granted to insofar as it seeks a judgment of acquittal, and it is conditionally granted to the extent it seeks a new trial.
2. The jury's guilty verdicts on Counts 1–5 of the Amended Superseding Indictment are SET ASIDE and a Judgment of Acquittal SHALL ISSUE.
3. The Sentencing that was set in for January 30, 2024 and all related dates and deadlines are VACATED.
4. To the extent predecessor charges or indictments remain open on the docket, they are DISMISSED.
5. After she enters the Judgment of Acquittal on the docket, the Clerk is DIRECTED to CLOSE THIS CASE.

DATED this 21 day of December, 2023

BY THE COURT:

James K. Bredar
Chief Judge