The Healthcare Law Section Presents

18th Annual Healthcare Law Compliance Symposium: Part III

Thursday, October 21, 2021
3:30 - 5:45 P.M.
Via Zoom
2.0 hours Gen. CLE Credit

Provider #36

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18th Annual Healthcare Law Compliance Symposium, Part III

Program Title
Healthcare Law

Section/Committee

Thursday, October 21, 2021 3:30 PM

Zoom Webinar

Program Date and Time
Event Location

Participant Name
State Bar Number
Profession, if not a lawyer

Please rate by circling the appropriate number ( 5 = highest rating; 1 = lowest rating )

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<th>Speakers</th>
<th>Usefulness of Information</th>
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Overall program rating ................................................................. 5  4  3  2  1

Contribution of written materials to the learning experience (Consider whether the material contained significant, current intellectual or practical content) ................................................................. 5  4  3  2  1

Contribution of the location/environment to the learning experience ................................................................. 5  4  3  2  1

Did the program meet your expectations?  
☐ Yes  ☐ No

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☐ Yes  ☐ No

If no, Please explain

How did you hear about the program?

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If other, Please explain

Please rank the factors that influenced your attendance at this program.

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Please sign this form and return to: Los Angeles County Bar Association, Events Department, P.O. Box 55020, Los Angeles, CA 90055-2020
Number of years in practice __________________
Number of lawyers in firm __________________

List of your area(s) of practice/interest
__________________________________________________________________________
__________________________________________________________________________

Who recommends/authorizes CLE attendance in your firm?
☐ Managing partner ☐ Recruiting officer ☐ Other ________________________________
☐ Department Head ☐ Self

What program length do you prefer?
☐ 1 Hour ☐ 2 Hours ☐ 3 Hours ☐ All-day

What time of day do you prefer to attend program?
☐ Weekday before 10 a.m. ☐ Weekday lunch ☐ Weekday evening
☐ Weekend ☐ Other ________________________________

Comments ________________________________________________________________

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Events Department, P.O. Box 55020, Los Angeles, CA 90055-2020
18th Annual Healthcare Law Compliance Symposium

Part III: October 21, 2021 from 3:30 - 5:45 p.m.

Session 1: The Latest in Healthcare Criminal and Civil Enforcement

- Roger A. Hsieh, Health Care Fraud Coordinator, Major Frauds Section, U.S. Attorney's Office, Central District of California
- Joshua M. Robbins, Buchalter

Session 2: Key Issues in Peer Review

- Nick Jurkowitz, Fenton Law Group
- David Balfour, Buchalter
Roger Hsieh is an Assistant United States Attorney in the Major Frauds Section at the United States Attorney’s Office in Los Angeles and serves as the Office’s Health Care Fraud Coordinator. As an AUSA, Roger investigates and prosecutes cases through trial and appeal involving white-collar crime, including health care fraud, violations of the anti-kickback statute, wire fraud, customs fraud, bank fraud, and money laundering. Before becoming an AUSA, Roger was an associate at O’Melveny where he represented healthcare, technology, and entertainment clients in litigation and white collar investigations. At O’Melveny, Roger also counseled clients on the Affordable Care Act, the Health Insurance Portability and Accountability Act (HIPAA), state privacy laws, anti-kickback laws, corporate practice of medicine laws, and data privacy and security. Prior to joining O’Melveny, Roger was a judicial law clerk to United States District Court Judge John Z. Lee for the Northern District of Illinois. Roger obtained his B.A. from Northwestern University and his J.D. from UCLA Law School. Prior to law school, Roger worked a project manager implementing electronic medical records.
Joshua M. Robbins

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Shareholder

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Areas of Practice & Industry Specialties
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Secrets & Employee Mobility

“A top-notch litigator; superb legal writer; and skilled wordsmith who transforms complex legal arguments into simple and compelling narratives in the courtroom.” – Benchmark Litigation

Josh Robbins, a former federal prosecutor, is the Chair of the Firm’s White Collar and Investigations Practice. Mr. Robbins has led trials, appeals, and investigations involving hundreds of millions of dollars and major government enforcement proceedings, representing Fortune 500 companies, sovereign governments, and prominent individuals. His matters have involved allegations of criminal healthcare fraud, False Claims Act violations, civil and criminal securities fraud, tax evasion, and bank fraud, as well as complex business disputes. Many of his cases have received national and international public attention, including matters reported in the Wall Street Journal, New York Times, Los Angeles Times, CNN, and CNBC. Benchmark Litigation has named him as a “California Litigation Star.”

Mr. Robbins previously served as an Assistant United States Attorney in the Central District of California, where he was lead counsel in various federal jury trials and appeals before the U.S. Court of Appeals for the Ninth Circuit, as well as numerous grand jury investigations of fraud, kickbacks, and corruption. Among other matters, he led the prosecution of a $900 million healthcare kickback scheme described as the largest insurance fraud case in California history. For his work on a major securities fraud trial, he was awarded the SEC’s Director’s Award for Criminal Coordination.

Before joining the Firm, Mr. Robbins also led the white collar defense practice of an elite boutique litigation firm, and practiced at two major international law firms, where he represented clients in matters ranging from Supreme Court appeals to international treaty-based arbitrations to DOJ and SEC investigations.

Mr. Robbins is a graduate of Harvard Law School and Harvard College. After law school, he served as law clerk for the Honorable Stanley Marcus of the U.S. Court of Appeals for the Eleventh Circuit.

Professional Activities

• President, Harvard Law School Association of Orange County

Representative Matters

Government Investigations and Enforcement

• Lead counsel for national medical supply company in DOJ investigation into suspected healthcare fraud and kickback scheme

• Lead counsel for health care provider in DOJ investigation of alleged fraud and kickback scheme, as well as related civil rights lawsuit and parallel $80 million civil litigation

• Co-lead counsel for plaintiff in major RICO lawsuit against global religious organization for human trafficking and forced labor violations
• Lead counsel for behavioral health company in investigation by state attorney general
• Lead counsel for marketing company and its CEO in SEC and DOJ investigations
• As prosecutor, led investigation and prosecution of $900 million healthcare kickback and public corruption investigation involving spinal surgeries
• As prosecutor, led trials of $170 million securities fraud scheme, $200 million tax fraud scheme, and $70 million health care fraud scheme

Business Trials and Appeals
• Lead counsel for multinational company in $200 million federal antitrust and RICO lawsuit
• Lead trial counsel for major national marketing company in $100 million arbitration involving fraud in M&A transaction
• Lead trial counsel for a Maltese investment company in a $200 million arbitration against the government of Austria
• Co-lead appellate and trial counsel for executive in $100 million dispute with auto dealership company regarding fraud, breach of fiduciary duty, and breach of contract
• Co-lead trial counsel for auto dealership executive in multi-million dollar arbitration against leading national dealership chain
• Co-lead counsel for IT services company in international litigation and arbitration regarding theft of trade secrets and breach of cross-border service contract

Publications
• UNLEASHING THE LEVIATHAN: Tips for Companies Referring Cases to Law Enforcement, *Buchalter Client Alert*, September 28, 2021
• Treasury’s New Bank Secrecy Act Whistleblower Program, January 25, 2021
• New Whistleblower Program May Lead to Surge in Bank Secrecy Act Enforcement, *Bloomberg Law*, January 22, 2021
• SEC Enforcement Expansion May Face Constitutional Limits, *Law360*, January 20, 2021
• Congress Makes Sweeping Changes to Money Laundering Enforcement, *Buchalter Client Alert*, January 4, 2021
• First Circuit Decision Underlines Risk of Criminal HIPAA Enforcement, *Buchalter Client Alert*, August 19, 2020
• From Frying Pan to Fire: Strategic Issues When Reimbursement Disputes Turn Into Criminal Investigations, *Buchalter Client Alert*, July 28, 2020
• DOJ Criminal Health Care Enforcement: It’s Not Just for Federal Programs Anymore, *Buchalter Client Alert*, July 14, 2020
• Flynn Dismissal Raises Bar(r) for False Statements Prosecutions, The Daily Journal, May 13, 2020
• COVID-19 Test Providers, Beware Kickback Enforcement Tool, Law360, April 16, 2020
• 5th Amendment Strategy For Parallel Civil, Criminal Litigation, Law360, August 8, 2019
• Taking the Fifth in Parallel Criminal and Civil Proceedings, Los Angeles Daily Journal, July 22, 2019
• New Lessons About Data Breaches And Insider Trading, Los Angeles Daily Journal, July 11, 2018
• Once More Unto The Breach, Criminal Justice, April 1, 2018
• Gag Orders on Grand Jury Subpoenas to Banks: The Next First Amendment Frontier?, California Lawyer, December 12, 2017
• In Microsoft Case, the Supreme Court Considers Law Enforcement Power in a Globalized and Digital World, Orange County Register, December 1, 2017
• Growing Risk of Insider Trading on Data Breaches, Los Angeles Daily Journal, October 19, 2017
• When Trade Secrets Cases Go Criminal: Part 2, Law360, June 28, 2017
• When Trade Secrets Cases Go Criminal: Part 1, Law360, June 27, 2017

Presentations
• Presenter, "The Latest in Healthcare Criminal and Civil Enforcement," LACBA’s 18th Annual Healthcare Law Compliance Symposium Part III, October 21, 2021
• Speaker, "Health Care Fraud Investigations: An Insider’s View," Orange County Bar Association, Health Care Section, October 10, 2019
• Speaker, "Stepping Through the Minefield: Legal and Ethical Issues in Internal Investigations," Orange County Bar Association, Corporate Counsel Section, July 8, 2019
• Speaker, "Hard Lessons in the MeToo Era," Orange County Bar Association, Corporate Counsel Section, July 18, 2018
• Speaker, "When Trade Secrets Go Criminal." Bridgeport CLE Webinar, November 2, 2017
• Speaker, "Hard Lessons from Recent Disasters Such as Wells Fargo and Yahoo," Orange County Bar Association, Corporate Counsel Section, August 8, 2017

Education
Mr. Robbins received his J.D., cum laude, from Harvard Law School. He received his M.A.L.D. from Tufts University, Fletcher School of Law and Diplomacy, and his A.B., magna cum laude, from Harvard College, where he was awarded the John Harvard Scholarship.

Bar Admissions
• California
• District of Columbia
• New York

Court Admissions
• U.S. Court of Appeals for the Ninth Circuit
• U.S. District Court for the Central District of California
• U.S. District Court for the District of Columbia
• U.S. District Court for the Northern District of California
1. COVID Fraud
2. Telehealth Fraud
3. Elder Fraud
4. Substance Use Treatment
5. Data Analysis in Enforcement
6. Subregulatory Guidance
7. Private Payers
8. False Claims Act Amendments Act
FOR IMMEDIATE RELEASE

DOJ Announces Coordinated Law Enforcement Action to Combat Health Care Fraud Related to COVID-19

Criminal Charges Against Telemedicine Company Executive, Physician, Marketers, and Medical Business Owners For COVID-19 Related Fraud Schemes with Losses Exceeding $143 Million

The Department of Justice today announced criminal charges against 14 defendants, including 11 newly-charged defendants and three who were charged in superseding indictments, in seven federal districts across the United States for their alleged participation in various health care fraud schemes that exploited the COVID-19 pandemic and resulted in over $143 million in false billings.
2021 Health Care Fraud National Enforcement Action:
Example of CARES Act Provider Relief Fund Scheme

1. Fraudster receives money from Provider Relief Fund.
2. Fraudster promises to comply with terms and conditions without treating actual or possible cases of COVID-19.
3. Fraudster uses the relief money for personal expenses – not for expenses related to the pandemic.

HHS → Fraudster → $ → Fraudster uses the relief money for personal expenses – not for expenses related to the pandemic.
Department of Justice
Office of Public Affairs

FOR IMMEDIATE RELEASE

Friday, September 17, 2021

National Health Care Fraud Enforcement Action Results in Charges Involving over 244 Billion in Alleged Loss

The charges target approximately $1.1 billion in fraud committed using telemedicine (the use of telecommunications technology to provide health care services remotely), $29 million in COVID-19 health care fraud, $133 million connected to substance abuse treatment facilities, or “sober homes,” and $100 million connected to other health care fraud and illegal opioid distribution schemes across the country.

“This nationwide enforcement action demonstrates that the Criminal Division is at the forefront of the fight against health care fraud and opioid abuse by prosecuting those who have exploited health care benefit programs and their patients for personal gain,” said Assistant Attorney General Kenneth A. Polite Jr. of the Justice Department’s Criminal Division. “The charges announced today send a clear deterrent message and should leave no doubt about the department’s ongoing commitment to ensuring the safety of patients and the integrity of health care benefit programs, even amid a continued pandemic.”
2021 Health Care Fraud National Enforcement Action: Example of Telemedicine Fraud Scheme

1. Offers free or low cost medical products or testing to beneficiary

2. Orders products or testing

3. Sells prescriptions to medical equipment company or laboratory, directly or indirectly

4. Medical equipment company or laboratory bills Medicare and pays kickback to telemedicine company

Telemedicine Company or Marketer

Telemedicine Doctor

Medical Equipment Company or Laboratory
2021 Health Care Fraud National Enforcement Action: Example of Sober Homes Fraud Scheme

1. Patients are recruited by body brokers in exchange for kickbacks.

2. Patients are frequently provided substances to qualify for high-reimbursing care, provided substandard treatment, and subjected to frequent and unnecessary testing.

3. A testing facility frequently pays kickbacks to the substance abuse treatment facility for tests that can be billed to insurance.

4. The substance abuse treatment facility and testing facility bill the patients' insurance.
IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 18-10991

D.C. Docket No. 9:15-cr-80049-KAM-1

UNITED STATES OF AMERICA,

Plaintiff - Appellee,

versus

SALOMON E. MELGEN,

Defendant - Appellant.

Appeal from the United States District Court for the Southern District of Florida

(July 31, 2020)

Before MARTIN, GRANT, and LAGOA, Circuit Judges.
MEMORANDUM FOR: HEADS OF ALL DEPARTMENT COMPONENTS
FROM: THE ATTORNEY GENERAL
SUBJECT: ISSUANCE AND USE OF GUIDANCE DOCUMENTS BY THE DEPARTMENT OF JUSTICE

This Memorandum revises and clarifies the principles that should govern the issuance and use of guidance documents by the Department of Justice.

I. Introduction

A guidance document is a statement of general applicability issued by an agency to inform the public of its policies or legal interpretations. Guidance documents may take a variety of forms, including certain interpretive memoranda and manuals, policy statements, opinion letters of general applicability, and other similar materials. As it is used here, the term “guidance document” does not include legislative rules; adjudicatory or administrative actions; rulings; legal advice or trainings directed at other federal agencies; internal policies and guidelines; or litigation filings.
To amend title 31, United States Code, to modify False Claims Act procedures, and for other purposes.

IN THE SENATE OF THE UNITED STATES

Mr. GRASSLEY (for himself, Mr. LEAHY, Mr. KENNEDY, Mr. DURBIN, and Mr. WICKER) introduced the following bill, which was read twice and referred to the Committee on ............

A BILL

To amend title 31, United States Code, to modify False Claims Act procedures, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the “False Claims Amendments Act of 2021”.

SEC. 2. FALSE CLAIMS PROCEDURE.

(a) Proving Materiality.—Section 3729 of title 31, United States Code, is amended by adding at the end the following:

“(e) Proving Materiality.—
FOR IMMEDIATE RELEASE

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“The multiple health care fraud schemes charged today describe theft from American taxpayers through the exploitation of the national emergency,” said Deputy Attorney General Lisa O. Monaco. “These medical professionals, corporate executives, and others allegedly took advantage of the COVID-19 pandemic to line their own pockets instead of providing needed health care services during this unprecedented time in our country. We are committed to protecting the American people and the critical health care benefits programs created to assist them during this national emergency, and we are determined to hold those who exploit such programs accountable to the fullest extent of the law.”

Additionally, the Center for Program Integrity, Centers for Medicare & Medicaid Services (CPI/CMS) separately announced today that it took adverse administrative actions against over 50 medical providers for their involvement in health care fraud schemes relating to COVID-19 or abuse of CMS programs that were designed to encourage access to medical care during the pandemic.

“Medical providers have been the unsung heroes for the American public throughout the pandemic,” said FBI Director Christopher Wray. “It’s disheartening that some have abused their authorities and committed COVID-19 related fraud against trusting citizens. The FBI, along with our federal law enforcement and private sector partners, are committed to continuing to combat healthcare fraud and protect the American people.”

The defendants in the cases announced today are alleged to have engaged in various health care fraud schemes designed to exploit the COVID-19 pandemic. For example, multiple defendants offered COVID-19 tests to Medicare beneficiaries at senior living facilities, drive-through COVID-19 testing sites, and medical offices to induce the beneficiaries to provide their personal identifying information and a saliva or blood sample. The defendants are alleged to have then misused the information and samples to submit claims to Medicare for unrelated, medically unnecessary, and far more expensive laboratory tests, including cancer genetic testing, allergy testing, and respiratory pathogen panel tests. In some cases, and as alleged, the COVID-19 test results were not provided to the beneficiaries in a timely fashion or were not reliable, risking the further spread of the disease, and the genetic, allergy, and respiratory pathogen testing was medically unnecessary, and, in many cases, the results were not provided to the patients or their actual primary care doctors. The proceeds of the fraudulent schemes were allegedly laundered through shell corporations and used to purchase exotic automobiles and luxury real estate.
“It’s clear fraudsters see the COVID-19 pandemic as a money-making opportunity — creating fraudulent schemes to victimize beneficiaries and steal from federal health care programs,” said Deputy Inspector General for Investigations Gary L. Cantrell of Health and Human Services – Office of Inspector General (HHS-OIG). “Our agency and its law enforcement partners are aggressively and effectively investigating these egregious crimes, which is made equally clear given the results of this takedown. We will continue to support the unprecedented COVID-19 public health effort by holding accountable people who use deceptive tactics to profit from the pandemic.”

In another type of COVID-19 health care fraud scheme announced today, defendants are alleged to have exploited policies that were put in place by CMS to enable increased access to care during the COVID-19 pandemic. For example, pursuant to the COVID-19 emergency declaration, telehealth regulations and rules were broadened so that Medicare beneficiaries could receive a wider range of services from their doctors without having to travel to a medical facility. The cases announced today include first in the nation charges for allegedly exploiting these expanded policies by submitting false and fraudulent claims to Medicare for sham telemedicine encounters that did not occur. As part of these cases, medical professionals are alleged to have offered and paid bribes in exchange for the medical professionals’ referral of medically unnecessary testing.

The law enforcement action today also includes the third set of criminal charges related to the misuse of Provider Relief Fund monies. The Provider Relief Fund is part of the Coronavirus Aid, Relief, and Economic Security (CARES) Act, a federal law enacted March 2020 designed to provide needed medical care to Americans suffering from COVID-19.

The Fraud Section is prosecuting the cases in the following districts: Western District of Arkansas, Northern District of California, Middle District of Louisiana, Central District of California, Southern District of Florida, District of New Jersey, and the Eastern District of New York.

Today’s enforcement actions were led and coordinated by Assistant Chief Jacob Foster and Trial Attorneys Rebecca Yuan and Gary A. Winters of the National Rapid Response Strike Force of the Health Care Fraud Unit of the Criminal Division’s Fraud Section, in conjunction with the Health Care Fraud Unit’s Medicare Fraud Strike Forces (MFSF) in Miami, Los Angeles, the Gulf Coast, and Brooklyn, as well as the U.S. Attorneys’ Offices for the Northern District of California, Western District of Arkansas, and Middle District of Louisiana.

The MFSF is a partnership among the Criminal Division, U.S. Attorneys’ Offices, the FBI and HHS-OIG. In addition, U.S. Postal Inspection Service, Internal Revenue Service Criminal Investigation, Veterans Affairs Office of Inspector General, Department of Defense Office of Inspector General, Federal Deposit Insurance Corporation, Louisiana Medicaid Fraud Control Unit, and other federal and state law enforcement agencies participated in the law enforcement action.

The law enforcement action was brought in coordination with the Health Care Fraud Unit’s COVID-19 Interagency Working Group, which is chaired by the National Rapid Response Strike Force and organizes efforts to address illegal activity involving health care programs during the pandemic.

The Fraud Section leads the Medicare Fraud Strike Force. Since its inception in March 2007, the Medicare Fraud Strike Force, which maintains 15 strike forces operating in 24 federal districts, has charged more than 4,200 defendants who have collectively billed the Medicare program for nearly $19 billion. In addition, the HHS Centers for Medicare and Medicaid Services, working in conjunction with the HHS-OIG, are taking steps to increase accountability and decrease the presence of fraudulent providers.

**Case Summaries**

**Western District of Arkansas**

- Billy Joe Taylor, 42, of Lavaca, Arkansas, was charged by criminal complaint with health care fraud in connection with an alleged scheme to defraud the United States of over $88 million, including over $42 million in false and fraudulent claims during the COVID-19 health emergency that were billed in combination with claims that were submitted for testing for COVID-19 and other respiratory illnesses. Taylor, the owner and operator of Vitas Laboratories LLC and Beach Tox LLC, two testing laboratories, allegedly used access to beneficiary and medical provider information from prior laboratory testing orders to submit fraudulent claims for urine drug tests and other laboratory tests, including respiratory pathogen panel and COVID-19 tests, that were not actually ordered or
performed. The complaint also alleges that hundreds of claims were submitted for beneficiaries after they had died or otherwise ceased providing samples. The case is being prosecuted by Senior Litigation Counsel James Hayes and Trial Attorney D. Keith Clouser of the National Rapid Response Strike Force, and Assistant U.S. Attorney Kenneth Elser of the U.S. Attorney’s Office for the Western District of Arkansas.

**Northern District of California**

- Mark Schena, 58, of Los Altos, California, the president of Arrayit Corporation, is charged along with two others, the Arrayit Vice President of Marketing and the President of an Arizona marketing organization, in connection with the submission of over $70 million in false and fraudulent claims for allergy and COVID-19 testing. The superseding indictment against Schena includes new counts of health care fraud, a conspiracy to pay kickbacks, and payment of kickbacks in connection with false and fraudulent statements about the existence, regulatory status, and accuracy of an Arrayit COVID-19 test. The conspiracy allegedly sought to induce the ordering of the Arrayit COVID-19 test and to bundle, i.e., require combination with, the COVID-19 test and Arrayit’s medically unnecessary allergy test. The COVID-19 test results were not provided in a timely fashion and were not reliable in detecting COVID-19. The cases are being prosecuted by Acting Principal Deputy Assistant Chief Justin Weitz of the Market Integrity and Major Fraud Unit of the Fraud Section, Assistant Chief Jacob Foster of the National Rapid Response Strike Force, and Assistant U.S. Attorney Wil Frentzen of the U.S. Attorney’s Office for the Northern District of California.

**Central District of California**

- Petros Hannesyan, 36, of Burbank, California, was charged with the theft of government property and wire fraud in connection with $229,454 that he obtained from COVID-19 relief programs. Hannesyan, the owner of Hollywood Home Health Services, Inc., a home health agency located in Los Angeles, allegedly misappropriated funds from the CARES Act Provider Relief Fund and submitted false loan applications and a false loan agreement to the Economic Injury Disaster Loan Program, rather than use the funds for COVID-19 patient care and to support small businesses experiencing disruption due to the COVID-19 pandemic. The case is being prosecuted by Trial Attorney Alexis Gregorian of the Los Angeles Strike Force.

**Southern District of Florida**

- Michael Stein, 35, and Leonel Palatnik, 42, both of Palm Beach County, Florida, were charged in connection with an alleged $73 million conspiracy to defraud the United States and to pay and receive health care kickbacks during the COVID-19 pandemic. Stein, the owner and operator of purported consulting company 1523 Holdings, LLC, and Palatnik, an owner and operator of Panda Conservation Group, LLC, a Texas company that owned and operated testing laboratories in Dallas and Denton, Texas, allegedly exploited temporary waivers of telehealth restrictions enacted during the pandemic by offering telehealth providers access to Medicare beneficiaries for whom they could bill consultations. In exchange, these providers agreed to refer beneficiaries to Panda’s laboratories for expensive and medically unnecessary cancer and cardiovascular genetic testing. The case is being prosecuted by Trial Attorney Ligia Markman of the National Rapid Response Strike Force.

- Juan Nava Ruiz, 44, and Eric Frank, 47, both of Coral Springs, Florida, were charged for an alleged $9.3 million health care kickback scheme, along with Christopher Licata, 44, of Boca Raton, Florida, who was previously charged in a separate Indictment. Licata, an owner of Boca Toxicology, LLC, a clinical laboratory based in Boca Raton, allegedly offered and paid kickbacks to patient brokers, including Ruiz and Frank, in exchange for referring Medicare beneficiaries to Boca Toxicology for various forms of genetic testing and other laboratory testing that they did not need, including the submission of $422,748 in claims related to medically unnecessary respiratory pathogen panel testing and genetic testing that was improperly bundled with COVID-19 testing. The cases are being prosecuted by Trial Attorney Jamie de Boer of the Miami Strike Force.

**Middle District of Louisiana**

- Malena Lepetich, 38, of Belle Chase, Louisiana, was charged for an alleged $15 million scheme to commit health care fraud, to defraud the United States, and to pay and receive health care kickbacks. Lepetich, the owner of MedLogic, LLC, a clinical laboratory based in Baton Rouge, Louisiana, allegedly solicited and received
kickbacks in exchange for referrals of urine specimens for medically unnecessary testing. Lepetich also allegedly offered to pay kickbacks for referrals of specimens for COVID-19 and respiratory pathogen testing. Finally, Lepetich allegedly caused the submission of over $10 million in claims to Medicare, Medicaid, and Blue Cross Blue Shield of Louisiana for panels of expensive respiratory testing that was medically unnecessary. The case is being prosecuted by Trial Attorney Justin M. Woodard of the Gulf Coast Strike Force and Assistant U.S. Attorney Kristen Craig of the U.S. Attorney's Office for the Middle District of Louisiana.

**District of New Jersey**

- Alexander Baldonado, 65, of Queens, New York, was charged with six counts of health care fraud. Baldonado, a medical doctor, allegedly participated in an event that advertised COVID-19 testing. In addition to authorizing the COVID-19 tests, Baldonado allegedly ordered expensive and medically unnecessary cancer genetic testing for Medicare beneficiaries who attended the event. Baldonado also allegedly billed Medicare for services, including lengthy office visits, that he never provided to these beneficiaries. Approximately $2 million in claims were submitted as a result of Baldonado's COVID-19 health care fraud scheme, and approximately $17 million in claims were submitted as a result of Baldonado's broader health care fraud scheme. The case is being prosecuted by Trial Attorney Rebecca Yuan of the National Rapid Response Strike Force.

- Donald Clarkin, 65, of Staten Island, New York, was charged in connection with a $5.4 million conspiracy to defraud the United States and pay and receive health care kickbacks. Clarkin, a partner at a diagnostic testing laboratory, allegedly exploited the pandemic by offering kickbacks in exchange for respiratory pathogen panel tests that would be improperly bundled with COVID-19 tests and billed to Medicare. Clarkin also allegedly paid and received kickbacks and bribes in exchange for arranging for the ordering of medically unnecessary genetic tests that were ineligible for Medicare reimbursement. The case is being prosecuted by Trial Attorney Rebecca Yuan of the National Rapid Response Strike Force.

**Eastern District of New York**

- Peter Khaim, 41, and Arkadiy Khaimov, 38, both of Forest Hills, New York, who owned and controlled several New York pharmacies and sham pharmacy wholesaling companies, were charged in a superseding indictment for their participation in an alleged $45 million health care fraud, wire fraud, and money laundering scheme. The defendants and their co-conspirators allegedly obtained billing privileges for multiple pharmacies by using nominees to serve as the purported owners and supervising pharmacists. The defendants then allegedly submitted false and fraudulent claims to Medicare, including by using COVID-19 “emergency override” billing codes to circumvent otherwise applicable pre-authorization requirements and limits on the frequency of refills for expensive drugs (primarily, the cancer treatment gels Targretin and Panretin). The defendants allegedly used an elaborate network of international money laundering operations to conceal and disguise the proceeds of the scheme. The case is being prosecuted by Trial Attorney Andrew Estes of the Brooklyn Strike Force.

The Department of Justice needs the public's assistance in remaining vigilant and reporting suspected fraudulent activity. To report suspected fraud, contact the National Center for Disaster Fraud (NCDF) at (866) 720-5721 or file an online complaint at: https://www.justice.gov/disaster-fraud/webform/ncdf-disaster-complaint-form. Complaints filed will be reviewed at the NCDF and referred to federal, state, local, or international law enforcement or regulatory agencies for investigation.

To learn more about the department's COVID response, visit: https://www.justice.gov/coronavirus. For further information on the Criminal Division's enforcement efforts on PPP fraud, including court documents from significant cases, visit the following website: https://www.justice.gov/criminal-fraud/ppp-fraud.

An indictment, complaint, or information is merely an allegation, and all defendants are presumed innocent until proven guilty beyond a reasonable doubt in a court of law.

**Topic(s):**
Coronavirus
Disaster Fraud
Health Care Fraud

Component(s):
Criminal Division
Criminal - Criminal Fraud Section
Office of the Deputy Attorney General
USAO - Arkansas, Western
USAO - California, Central
USAO - California, Northern
USAO - Florida, Southern
USAO - Louisiana, Middle
USAO - New Jersey
USAO - New York, Eastern

Press Release Number:
21-486

Updated May 26, 2021
FOR IMMEDIATE RELEASE Friday, September 17, 2021

National Health Care Fraud Enforcement Action Results in Charges Involving over $1.4 Billion in Alleged Losses

The Department of Justice announced today criminal charges against 138 defendants, including 42 doctors, nurses, and other licensed medical professionals, in 31 federal districts across the United States for their alleged participation in various health care fraud schemes that resulted in approximately $1.4 billion in alleged losses.

The charges target approximately $1.1 billion in fraud committed using telemedicine (the use of telecommunications technology to provide health care services remotely), $29 million in COVID-19 health care fraud, $133 million connected to substance abuse treatment facilities, or “sober homes,” and $160 million connected to other health care fraud and illegal opioid distribution schemes across the country.

“This nationwide enforcement action demonstrates that the Criminal Division is at the forefront of the fight against health care fraud and opioid abuse by prosecuting those who have exploited health care benefit programs and their patients for personal gain,” said Assistant Attorney General Kenneth A. Polite Jr. of the Justice Department’s Criminal Division. “The charges announced today send a clear deterrent message and should leave no doubt about the department’s ongoing commitment to ensuring the safety of patients and the integrity of health care benefit programs, even amid a continued pandemic.”

Today’s enforcement actions were led and coordinated by the Health Care Fraud Unit of the Criminal Division’s Fraud Section, in conjunction with its Health Care Fraud and Appalachian Regional Prescription Opioid (ARPO) Strike Force program and its core partners, the U.S. Attorneys’ Offices, Department of Health and Human Services Office of Inspector General (HHS-OIG), FBI, and Drug Enforcement Administration (DEA), as part of the department’s ongoing efforts to combat the devastating effects of health care fraud and the opioid epidemic. The cases are being prosecuted by Health Care Fraud and ARPO Strike Force teams from the Criminal Division’s Fraud Section, in coordination with 31 U.S. Attorneys’ Offices nationwide, and agents from HHS-OIG, FBI, DEA, and other federal and state law enforcement agencies.

“Health care fraud targets the vulnerable in our communities, our health care system, and our basic expectation of competent, available care,” said Assistant Director Calvin Shivers of the FBI’s Criminal Investigative Division. “Despite a continued pandemic, the FBI and our law enforcement partners remain dedicated to safeguarding American taxpayers and businesses from the steep cost of health care fraud.”

“We have seen all too often criminals who engage in health care fraud — stealing from taxpayers while jeopardizing the health of Medicare and Medicaid beneficiaries,” said Deputy Inspector General for Investigations Gary L. Cantrell of HHS-OIG. “Today’s announcement should serve as another warning to individuals who may be considering engaging in such illicit activity: our agency and its law enforcement partners remain unrelenting in our commitment to rooting out fraud, holding bad actors accountable, and protecting the millions of beneficiaries who rely on federal health care programs.”
“Holding to account those responsible for health care fraud and diversion of prescription drugs is a priority for DEA,” said DEA Administrator Anne Milgram. “These fraudulent activities prey on our most vulnerable — those in pain, the substance-addicted, and even the homeless — those who are most susceptible to promises of relief, recovery, or a new start. Not only do these schemes profit from desperation, but they often leave their victims even deeper in addiction. We are grateful to our partners who stand with us to keep our communities safer and healthier through our collective efforts to prevent the misuse and over-prescribing of controlled medications.”

“Every dollar saved is critical to the sustainability of our Medicare programs and meeting the needs of seniors and people with disabilities,” said Centers for Medicare & Medicaid Services (CMS) Administrator Chiquita Brooks-LaSure. “CMS has taken actions against 28 providers on behalf of people with Medicare coverage and to protect the Medicare Trust Fund. Actions like this to combat fraud, waste and abuse in our federal programs would not be possible without the successful partnership of Centers for Medicare & Medicaid Services, the Department of Justice and the U.S. Department of Health and Human Services, Office of Inspector General.”

**Telemedicine Fraud Cases**

The largest amount of alleged fraud loss charged in connection with the cases announced today — over $1.1 billion in allegedly false and fraudulent claims submitted by more than 43 criminal defendants in 11 judicial districts — relates to schemes involving telemedicine. According to court documents, certain defendant telemedicine executives allegedly paid doctors and nurse practitioners to order unnecessary durable medical equipment, genetic and other diagnostic testing, and pain medications, either without any patient interaction or with only a brief telephonic conversation with patients they had never met or seen. Durable medical equipment companies, genetic testing laboratories, and pharmacies then purchased those orders in exchange for illegal kickbacks and bribes and submitted over $1.1 billion in false and fraudulent claims to Medicare and other government insurers. In some instances, medical professionals billed Medicare for sham telehealth consultations that did not occur as represented. The proceeds of the scheme were spent on luxury items, including vehicles, yachts, and real estate.

The continued focus on prosecuting health care fraud schemes involving telemedicine reflects the success of the nationwide coordinating role of the Fraud Section’s National Rapid Response Strike Force, the creation of which was announced at the 2020 National Health Care Fraud and Opioid Takedown. The National Rapid Response Strike Force helped coordinate the prosecution of the telemedicine initiative, Sober Homes initiative, and COVID-19 cases that were announced today. The focus on telemedicine fraud also builds on the telemedicine component of last year’s national takedown and the impact of the 2019 “Operation Brace Yourself” Telemedicine and Durable Medical Equipment Takedown, which resulted in an estimated cost avoidance of more than $1.9 billion in the amount paid by Medicare for orthotic braces in the 20 months following that takedown.

**COVID-19 Fraud Cases**

Nine defendants in the cases announced today are alleged to have engaged in various health care fraud schemes designed to exploit the COVID-19 pandemic, which resulted in the submission of over $29 million in false billings. In one type of scheme, defendants are alleged to have exploited policies that were put in place by the CMS to enable increased access to care during the COVID-19 pandemic, such as expanded telehealth regulations and rules. Defendants allegedly misused patient information to submit claims to Medicare for unrelated, medically unnecessary, and expensive laboratory tests, including cancer genetic testing.

The law enforcement action today also includes criminal charges against five defendants who allegedly engaged in the misuse of Provider Relief Fund monies. The Provider Relief Fund is part of the Coronavirus Aid, Relief, and Economic Security (CARES) Act, a federal law enacted March 2020 designed to provide needed medical care to Americans suffering from COVID-19. The defendants allegedly used the moneys for their own personal expenses, including for gambling at a Las Vegas casino and paying a luxury car dealership.

The COVID-19 cases announced today build upon the success of the COVID-19 Health Care Fraud Takedown on May 26, a coordinated law enforcement action against 14 defendants in seven judicial districts for over $128 million in false
The law enforcement action and the cases announced today were brought in coordination with the Health Care Fraud Unit's COVID-19 Interagency Working Group, which is chaired by the National Rapid Response Strike Force and organizes efforts to address illegal activity involving health care programs during the pandemic.

**Sober Homes Cases**

The sober homes cases are announced on the one-year anniversary of the first ever national sober homes initiative in 2020, which included charges against more than a dozen criminal defendants in connection with more than $845 million of allegedly false and fraudulent claims for tests and treatments for vulnerable patients seeking treatment for drug and/or alcohol addiction. The over $133 million in false and fraudulent claims that are additionally alleged in cases announced today reflect the continued effort by the National Rapid Response Strike Force and the Health Care Fraud Unit's Los Angeles Strike Force, with the participation of the U.S. Attorneys' Offices for the Central District of California and the Southern District of Florida, to prosecute those who participated in illegal kickback and bribery schemes involving the referral of patients to substance abuse treatment facilities; those patients could be subjected to medically unnecessary drug testing – often billing thousands of dollars for a single test – and therapy sessions that frequently were not provided, and which resulted in millions of dollars of false and fraudulent claims being submitted to private insurers.

**Cases Involving the Illegal Prescription and/or Distribution of Opioids and Cases Involving Traditional Health Care Fraud Schemes**

The cases announced today involving the illegal prescription and/or distribution of opioids involve 19 defendants, including several charges against medical professionals and others who prescribed over 12 million doses of opioids and other prescription narcotics, while submitting over $14 million in false billings. The cases that fall into more traditional categories of health care fraud include charges against over 60 defendants who allegedly participated in schemes to submit more than $145 million in false and fraudulent claims to Medicare, Medicaid, TRICARE, and private insurance companies for treatments that were medically unnecessary and often never provided.

Prior to the charges announced as part of today’s nationwide enforcement action and since its inception in March 2007, the Health Care Fraud Strike Force, which maintains 15 strike forces operating in 24 districts, has charged more than 4,600 defendants who have collectively billed the Medicare program for approximately $23 billion. In addition to the criminal actions announced today, CMS, working in conjunction with HHS-OIG, announced 28 administrative actions to decrease the presence of fraudulent providers.

A complaint, information or indictment is merely an allegation, and all defendants are presumed innocent until proven guilty beyond a reasonable doubt in a court of law.


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**Topic(s):**
- Coronavirus
- Disaster Fraud
- Opioids
- Health Care Fraud

**Component(s):**
- Criminal Division
- Criminal - Criminal Fraud Section

**Press Release Number:**

Updated September 17, 2021
MEMORANDUM FOR: HEADS OF ALL DEPARTMENT COMPONENTS
FROM: THE ATTORNEY GENERAL
SUBJECT: ISSUANCE AND USE OF GUIDANCE DOCUMENTS BY THE DEPARTMENT OF JUSTICE

This Memorandum revises and clarifies the principles that should govern the issuance and use of guidance documents by the Department of Justice.

I. Introduction

A guidance document is a statement of general applicability issued by an agency to inform the public of its policies or legal interpretations. Guidance documents may take a variety of forms, including certain interpretive memoranda and manuals, policy statements, opinion letters of general applicability, and other similar materials. As it is used here, the term "guidance document" does not include legislative rules; adjudicatory or administrative actions; rulings; legal advice or trainings directed at other federal agencies; internal policies and guidelines; or litigation filings.

By definition, guidance documents "do not have the force and effect of law." Perez v. Mortgage Bankers Ass'n, 575 U.S. 92, 97 (2015) (quoting Shalala v. Guernsey Mem'l Hosp., 514 U.S. 87, 99 (1995)). Unlike rules promulgated through the notice and comment process, therefore, guidance documents do not bind the public and are not treated as binding by the courts. But guidance documents still serve many valuable functions. For example, interpretive guidance can "advise the public' of how the agency understands, and is likely to apply, its binding statutes and legislative rules." Kisor v. Wilkie, 139 S. Ct. 2400, 2420 (2019) (plurality opinion) (quoting Perez, 575 U.S. at 97). Guidance may also help explain an agency’s programs and policies or communicate other important information to regulated entities and the public. Guidance can collect related statutes, regulations, and other requirements in a single place. And guidance materials often convey important information to the public in language that is clearer and more accessible than the underlying statutes and regulations. Guidance documents can thus serve as an important tool to promote transparency, fairness, and efficiency.

II. Rescission of previous Memoranda

Two recent Memoranda substantially changed the Department’s traditional approach to guidance documents by establishing new review and approval conditions, and by placing additional restrictions and requirements on both publishing and relying on agency guidance. See Memorandum from the Attorney General, Prohibition on Improper Guidance Documents (Nov.
Memorandum for Heads of All Department Components

Issuance and Use of Guidance Documents by the Department of Justice

16, 2017) ("November 2017 Memorandum"); Memorandum from the Associate Attorney
General, Limiting Use of Agency Guidance Documents in Affirmative Civil Enforcement Cases
(Jan. 25, 2018) ("January 2018 Memorandum"). Changes consistent with these memoranda
were incorporated into the Justice Manual in 2018 and the Code of Federal Regulations in 2020.
See JM 1-19.000; JM 1-20.100 to 1-20.205; 28 C.F.R. §§ 50.26 and 50.27 (2020). As explained
in an Interim Final Rule being issued contemporaneously with this Memorandum, the procedures
imposed by the November 2017 and January 2018 Memoranda are overly restrictive; the
Memoranda and the implementing regulations have discouraged the development of valuable
guidance; and the Memoranda and regulations have also generated collateral disputes and
otherwise hampered Department attorneys when litigating cases where there is relevant agency
guidance.

By this Memorandum, I am rescinding the November 2017 and January 2018
Memoranda. I further direct the Department to initiate the process to revise the Justice Manual
to be consistent with this Memorandum, which sets forth the Department’s policy regarding the
issuance and use of guidance documents.

III. Principles for issuing and using guidance documents

Going forward, including in all currently pending litigation, the following principles
should govern the Department’s issuance of guidance documents and, as appropriate, the
Department’s use of guidance documents issued by both the Department and other agencies:

- The Department’s guidance documents should be drafted with the recognition that
they do not bind the public (except where binding by operation of a grant award or
contract) or have the force and effect of law. Guidance documents may, however, set
forth the Department’s interpretation of binding regulations, statutes, and
constitutional provisions. To reflect this distinction, Department components shall, to
the greatest extent practicable: (i) label a document as guidance when it is intended as
such; and (ii) cite the source of any binding legal requirements the guidance is
describing.

- In the enforcement context, an agency guidance document by itself “never forms ‘the
basis for an enforcement action’” because such documents cannot “impose any
‘legally binding requirements’ on private parties.” Kisor, 139 S. Ct. at 2420 (plurality
opinion) (citation omitted). Instead, enforcement actions must be based on the failure
to comply with a binding obligation, such as one imposed by the Constitution, a
statute, a legislative rule, or a contract. See, e.g., id. But Department attorneys
handling an enforcement action (or any other litigation) may rely on relevant
guidance documents in any appropriate and lawful circumstances, including when a
guidance document may be entitled to deference or otherwise carry persuasive weight
with respect to the meaning of the applicable legal requirements. \textit{See id.}; \textit{see also id.} at 2424–25 (Roberts, C.J., concurring in part). To the extent guidance documents are relevant to claims or defenses in litigation, Department attorneys are free to cite or rely on such documents as appropriate.

- The Department’s guidance documents should be clear, transparent, and readily accessible to the public. Department components are free to post guidance and other public-facing materials on their own websites. In addition, whenever practicable, Department components should continue posting materials to the Department’s Online Guidance Portal, \url{https://www.justice.gov/guidance}; guidance documents posted there should contain unique numbers and include issuance and revision dates. While the Guidance Portal is intended for guidance documents, Department components may submit to the portal other public-facing materials that are published elsewhere when the publication of those materials on the Guidance Portal would benefit the public.

- The Department’s guidance documents should reflect the breadth of expertise within the Department and should be drafted in a way that does not create inconsistencies among different components. I am directing the Office of Legal Policy to work with all relevant Department components to develop recommendations for an appropriate procedure to accomplish these goals. Those recommendations will be submitted to the Office of the Deputy Attorney General and the Office of the Attorney General for review and concurrence three months from the date of this Memorandum.

This Memorandum provides internal Department direction only. It is not intended to, does not, and may not be relied upon to create any rights, substantive or procedural, enforceable by law by any party in any matter or proceeding. Nor does it place any limitations on otherwise lawful litigation prerogatives of the Department of Justice.
IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

No. 18-10991

D.C. Docket No. 9:15-cr-80049-KAM-1

UNITED STATES OF AMERICA,

Plaintiff - Appellee,

versus

SALOMON E. MELGEN,

Defendant - Appellant.

________________________________________

Appeal from the United States District Court for the Southern District of Florida

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(July 31, 2020)

Before MARTIN, GRANT, and LAGOA, Circuit Judges.

GRANT, Circuit Judge:

Salomon Melgen, an ophthalmologist practicing in Palm Beach County, was charged in a 76-count indictment broadly alleging that he operated a multi-year
scheme to defraud Medicare. At trial, the government argued that Melgen had systematically diagnosed his patients incorrectly and prescribed medically unnecessary treatments. After nine counts were dismissed for multiplicity, the jury found Melgen guilty on each of the other 67 counts. The district court sentenced Melgen to 204 months of imprisonment (below the Guidelines range of 235–293 months) and also ordered restitution.

Melgen filed a notice of appeal. He also filed a motion for a new trial alleging newly discovered evidence, along with a motion for bond pending appeal. The court denied both of Melgen’s motions, and this appeal followed. On appeal, Melgen brings us a laundry list of perceived bases for reversal—including challenges to a jury instruction about materiality, the introduction of summary charts at trial (alongside a host of other miscellaneous evidentiary issues), the sufficiency of the evidence, the court’s denial of a new trial, and the reasonableness of his sentence. We affirm the district court’s judgment in all respects.

I.

Salomon Melgen operated a high-volume practice as an eye doctor. A significant portion of his practice focused on age-related macular degeneration, or ARMD. There are two varieties of ARMD—“wet” and “dry.” Typically, only 10 to 15% of those diagnosed with ARMD have the wet version of the disease. But Melgen’s treatment records told a different story. Of the rather remarkable 97.8% of his patients that he diagnosed with ARMD, he also diagnosed 75.5% with wet ARMD in at least one eye. That included almost all of his African-American
patients, even though expert testimony at trial indicated that wet ARMD is “nearly exclusively a disease of Caucasians,” and thus almost never present in the African-American population.

Dry ARMD is basically untreatable, but wet ARMD may be slowed or stopped by so-called anti-VEGF drugs.\(^1\) One recognized anti-VEGF treatment for wet ARMD is a drug called Lucentis. A single vial of Lucentis costs approximately $2,000. Between 2008 and 2013, Melgen’s practice collected nearly $57 million from Medicare for administering Lucentis. By contrast, Melgen only rarely prescribed Avastin, another drug recognized as a treatment for wet ARMD that costs only $50.

Long before this criminal case began, Melgen was involved in litigation regarding his preferred method for prescribing and administering Lucentis—a method known as “multi-dosing.” See *Vitreo Retinal Consultants of the Palm Beaches, P.A. v. U.S. Dep’t of Health & Human Servs.*, 649 F. App’x 684, 687 (11th Cir. 2016). Medicare’s reimbursement rate to medical providers for Lucentis is based on the fact that each vial of Lucentis is intended to provide a single dose of solution for a single eye. See *id.* But Melgen argued that each vial held enough of the drug to safely administer multiple doses to separate patients from one vial—and indeed, this was how he administered the drug. This created a billing-and-compensation issue with Medicare. On the one hand, Melgen could argue that Medicare’s total costs were the same regardless of whether he multi-dosed or single-dosed, because Medicare paid Melgen the ordinary per-patient rate for

\(^1\) VEGF stands for “Vascular endothelial growth factor.”
Lucentis either way. On the other hand, Medicare’s rate of payment was based in part on the expected cost to the provider, so Melgen received a windfall relative to his expenditures by multi-dosing. And this windfall was substantial—by extracting up to three doses from a single vial, Melgen’s practice “was ‘reimbursed’ for approximately $6,075 per single Lucentis vial, three times the average cost of the vial and three times the amount it would have received had it administered the drug according to the label.” *Id.* at 688.

Melgen was instructed to repay Medicare millions of dollars for this practice in June of 2009 after Medicare notified Melgen that multi-dosing misrepresented his expenses and was medically unreasonable. *Id.* He then filed a suit seeking the return of those funds, arguing that Medicare’s interpretation of its regulations was unreasonable. In 2016, we ruled against Melgen and affirmed Medicare’s interpretations as not arbitrary or capricious. *See id.* at 687. As relevant to this appeal, the government suggested at trial that Melgen continued multi-dosing Lucentis until 2013.

Melgen also billed Medicare for numerous applications of focal laser photocoagulation, a procedure to treat wet ARMD where a high-intensity laser light is aimed at the eye. The government presented evidence at trial that the procedure is now almost never medically necessary given the effectiveness of anti-VEGF drugs.

Melgen was charged with Medicare fraud in a 76-count indictment. The charges generally outlined a scheme in which Melgen systematically over-diagnosed wet ARMD. The government alleged that Melgen billed Medicare for
treatments to patients that did not need them—whether because they were completely healthy, because they had dry ARMD, or because the particular eye he claimed to treat in his records was either fully blind or a prosthetic. In one case, for example, Melgen billed Medicare 96 times for treatment on a single patient’s prosthetic eye. The government also alleged that the scheme involved “pre-filling” some patient files so that ARMD was a default diagnosis even before Melgen met with a patient—including pre-drawing depictions of the patient’s retina, even though those drawings purported to depict the condition of the eye as seen on a particular (and necessarily later) day.

Counts 1–46 of the indictment alleged that Melgen knowingly and willfully executed a scheme to defraud Medicare and to obtain, by means of materially false and fraudulent representations, money controlled by Medicare. Counts 47–65 alleged that Melgen knowingly made or caused to be made false and fraudulent Medicare reimbursement claims that were medically unreasonable and unnecessary. Counts 66–76 alleged that Melgen knowingly and willfully made and used materially false documents while knowing that they contained materially false and fraudulent statements and entries in connection with the delivery of and payment for healthcare benefits. These counts covered particular entries in Medicare charts wherein Melgen falsely diagnosed patients with wet ARMD.

Melgen’s case proceeded to trial. We will briefly recount those parts of the eight-week trial that are most relevant to the issues raised on appeal. As part of its case, the prosecution introduced summary charts of Medicare records under Rule 1006 to demonstrate that Melgen’s practices were markedly different from
similarly situated physicians. See Fed. R. Evid. 1006. Those records were compiled by drawing out particular doctors’ data from raw Medicare data. In order to make the summaries relevant, the government pulled the data for only those self-identified ophthalmologists who (1) billed Medicare for over 500 injections of Lucentis from 2008–2013, (2) had at least 2,000 Medicare patients during that time, and (3) billed at least one claim each of those years.

Melgen, who had sought to exclude the charts in limine, renewed his objection, arguing that the charts were prejudicial, that they were barred as testimonial hearsay, and that no evidence supported the comparison criteria. For its part, the government argued that it had explained its comparator criteria through the testimony of Dr. Stuart Fine, a retina specialist from Colorado. Dr. Fine endorsed the 500-injection cutoff—which would equal roughly 83 injections per year over a six-year time span—but he rephrased it as “a hundred a year, basically.” The government also introduced testimony regarding that criterion from Dr. Julia Haller, an expert ophthalmologist based in Philadelphia. She testified that 500 injections of Lucentis over a six-year period would be a conservative estimate for identifying other retinal specialists. The district court admitted the charts. The witness who had prepared the charts then testified that the requirement that the comparators had treated 2,000 patients per year was based on Melgen’s own patient population of slightly more than 2,000 patients during the relevant period, and that the requirement of treating one patient per year during the period ensured that the sample did not include doctors that had not practiced throughout the relevant period.
As part of the evidence indicating that Melgen had falsely treated patients, the government called two witnesses, Delores Griffith and her daughter Susanne Perry, who insisted that Griffith had never received a particular eye surgery from Melgen on a particular date. Melgen correctly countered that records from an anesthetist corroborated that the surgery occurred, and argued that the testimony was undisclosed extrinsic bad act evidence prohibited by Rule 404(b) in any event.

In response, the district court issued a curative instruction:

On Thursday of last week, the prosecution introduced testimony from Delores Griffith and Susanne Perry in which both witnesses claimed that a surgical procedure performed by Dr. Melgen on May 21st of 2009, known as a vitrectomy, had not occurred. Evidence in Ms. Griffith’s patient file indicates that the procedure was performed on that date, and billing records show that both Dr. Melgen and the separate surgical center had billed Medicare for the procedure. So you, as the jury, are to disregard the witnesses’ testimony about that procedure and you should strike it from your minds and give it no weight. So I ask you to follow that instruction.

Other evidence at trial included patient records taken from a sample of Melgen’s bills. The parties contested whether that sample was statistically representative. The district court eventually instructed the jury that the sample was random, although not statistically guaranteed to be representative (later, at sentencing, the district court did conclude that the sample was representative to a 95% confidence interval).

The Eleventh Circuit’s pattern jury instruction for Melgen’s offenses says that a fact is material “if it has the capacity or natural tendency to influence a person’s decision. It doesn’t matter whether the decision-maker actually relied on the statement or knew, or should have known, that the statement was false.” But
before jury deliberations began, Melgen offered a lengthy new instruction based on a recent Supreme Court case addressing civil qui tam actions under the False Claims Act. See Universal Health Services, Inc. v. United States ex rel. Escobar, 136 S. Ct. 1989, 2002 (2016). The district court denied the requested alteration, noting that no similar case had adopted the proposed instruction and that the proposed instruction lacked a factual basis.

Melgen was convicted on all counts after an eight-week jury trial. The district court denied Melgen’s initial motions for judgment of acquittal and for a new trial.

Sentencing was next. Melgen had no prior convictions, and applying § 2B1.1 of the United States Sentencing Guidelines, the presentencing investigation report (PSR) set Melgen’s base offense level at 6. It then found that Melgen was responsible for a loss of between $65 and $150 million, leading to a 24-level increase. U.S.S.G. § 2B1.1(b)(1)(M). The PSR also incorporated various adjustments and enhancements, including for the large number of victims and abuse of trust; those raised Melgen’s total offense level to 42.

Melgen objected that the PSR applied the wrong loss calculation methodology and that it wrongfully included Medicare funds that he had already repaid to Medicare. The district court denied Melgen’s objection to the loss calculation method and found that the starting point for calculating the loss amount was the amount sought in the fraudulent bills Melgen submitted to Medicare, not the allowed amount or amount that Medicare actually paid. The court next found that the government had presented credible evidence establishing a statistically
reliable basis for concluding that the government’s loss calculation was a reasonable estimate of Melgen’s fraudulent billing. Because the record contained no sampling of patients from 2008, 2009, and 2013, the court decided to limit the loss calculation to the 2010 to 2012 time period. The court then found that the total amount Melgen fraudulently billed Medicare during those three years was $73,417,620. The court concluded that the mere fact that Melgen’s treatment could possibly have benefitted other undiagnosed conditions his patients may (or may not) have had was insufficient to rebut the loss calculation; those other conditions were not specified in the patient’s records and amounted to pure speculation in the court’s view.

At the same time, some of the sentencing decisions were in his favor. The court sustained Melgen’s objections to the PSR’s two-level enhancement for abusing the vulnerable and to its two-level enhancement for conduct involving a conscious or reckless risk of death or serious bodily injury. It therefore concluded that Melgen had an offense level of 38 and was in criminal history category I, with a Guidelines range of 235–293 months.

The district court varied downward and imposed a 204-month sentence. It eventually ordered $52,997,442 in restitution. The court also later denied a motion for bond pending appeal and for a new trial due to alleged newly discovered Brady evidence. Melgen now appeals.

II.

Melgen’s first argument on appeal is that the district court erred by giving the Eleventh Circuit’s pattern jury instruction on materiality. We review de novo
the legal correctness of a jury instruction, but review “questions of phrasing” and the denial of a requested instruction for an abuse of discretion. *United States v. Dulcio*, 441 F.3d 1269, 1275 (11th Cir. 2006); *United States v. Prather*, 205 F.3d 1265, 1270 (11th Cir. 2000) (citations omitted).

Our pattern jury instruction is based on the rule that a “false statement is material if it has a natural tendency to influence,” or is “capable of influencing,” the “decision of the decisionmaking body to which it was addressed.” *United States v. Henderson*, 893 F.3d 1338, 1346 (11th Cir. 2018) (internal quotation marks omitted) (quoting *Kungys v. United States*, 485 U.S. 759, 770 (1988)).

Melgen argues that the district court should have instead included his proposed language from *Escobar*—that materiality “looks to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.” *Escobar*, 136 S. Ct. at 2002 (alteration adopted and citation omitted).

*Escobar*, however, does not lend him any aid. First, some background on that case. Under the False Claims Act the government (and often an employee or other knowledgeable person who reveals misdeeds) can recover for fraudulent claims against the government. One theory under which these suits sometimes proceed is known as “implied false certification.” *Escobar* addressed the ins and outs of that theory, which is grounded in the idea that, “when a defendant submits a claim, it impliedly certifies compliance with all conditions of payment.” *Id.* at 1995. “But if that claim fails to disclose the defendant’s violation of a material statutory, regulatory, or contractual requirement, so the theory goes, the defendant has made a misrepresentation that renders the claim ‘false or fraudulent’”—thereby
triggering liability under the Act. *Id.* In that context, the Supreme Court noted that materiality looks to “the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.” *Id.* at 2002. That is the statement on which Melgen relies.

But it does not help him. To begin, we are not at all sure that *Escobar* didn’t approve of the objective standard that our current materiality standard is based on. “Capable of influencing” is not so very different than looking to the “effect on the likely or actual behavior” of the actor. Moreover, the *Escobar* standard for materiality is not made out of whole cloth. Following the statement that Melgen relies on, the Supreme Court tied the concept to our understanding of materiality in tort and contract. *See id.* at 2002–03. As part of that discussion, it explicitly referenced the—objective—“reasonable man” standards in both tort and contract. *Id.* The Court explained, for instance, that in tort the materiality of a statement may be shown where “a reasonable man would attach importance to [it] in determining his choice of action” and that materiality “in contract law is substantially similar.” *Id.*

Even if that were not sufficient—which we doubt—*Escobar* was addressing quite a different question than the one we face here. One of the key issues in that case was whether a misrepresentation or omission that technically qualified as a “condition of payment” would lead to liability even where the government would never actually refuse to pay on that basis. The answer was no, and the discussion of materiality was geared toward addressing that issue.
Which is, of course, a far cry from the criminal fraud statutes that Melgen faces. We are not the first to notice this distinction. In two cases since Escobar, the Fourth Circuit has examined whether the precise statement from Escobar that Melgen latches onto actually alters the long-standing objective materiality standard in criminal fraud cases. See United States v. Raza, 876 F.3d 604, 619–20 (4th Cir. 2017); United States v. Palin, 874 F.3d 418, 423 (4th Cir. 2017). According to that court? Doubtful. Like the Fourth Circuit, we think it unlikely that “the Court’s examination of how materiality applies under ‘implied false certification’ FCA cases transfers to all cases charging fraud, or even all cases charging health care fraud.” Palin, 874 F.3d at 423. And we have continued to rely on the standard articulated in our pattern jury instruction for materiality in criminal cases post-Escobar without requiring an alteration. See Henderson, 893 F.3d at 1346.

Moreover, Melgen cannot show a factual basis for his requested instruction even under his proposed interpretation of Escobar’s standard. Melgen billed for certain services, and Medicare paid for certain services in reliance on those bills. Melgen did not put forward evidence that Medicare routinely pays for treatment based on an incorrect diagnosis, if only it is possible that the patient had some other condition that the treatment would have aided—far from it. And that is enough to conclude that Escobar does not help him deal with the materiality, or lack thereof, of his false statements. For these reasons, we conclude both that the district court did not err in refusing to give Melgen’s proposed instruction and that any alleged error would have been harmless.
Melgen next argues that the district court erred by allowing the introduction of summary charts comparing Melgen’s billing to peer physicians. He sets out several potential rationales: the charts were not covered by Rule 1006, the evidence was testimonial hearsay in violation of the Confrontation Clause (or at least otherwise inadmissible hearsay), and the charts should have required expert evaluation under Rule 702. Evidentiary rulings are reviewed for both abuse of discretion and harmless error. See United States v. Maxwell, 579 F.3d 1282, 1295–96, 1298 (11th Cir. 2009). We review the admission of evidence for plain error where a defendant failed to make a particular objection at trial. United States v. Hoffman-Vaile, 568 F.3d 1335, 1341 (11th Cir. 2009). Confrontation Clause rulings are reviewed de novo and subject to constitutional harmless error analysis. United States v. Curbelo, 726 F.3d 1260, 1271–72 (11th Cir. 2013); United States v. Jones, 601 F.3d 1247, 1264 (11th Cir. 2010).

Where, as here, the underlying evidence is made up of voluminous Medicare claims, a district court has good reason to apply Rule 1006 to allow a summary chart. “Summary charts are permitted generally by Federal Rule of Evidence 1006 and the decision whether to use them lies within the district court’s discretion.” United States v. Richardson, 233 F.3d 1285, 1293 (11th Cir. 2000). Under that rule, “the essential requirement is not that the charts be free from reliance on any assumptions, but rather that these assumptions be supported by evidence in the record.” Id. at 1294 (quoting United States v. Diez, 515 F.2d 892, 905 (5th Cir. 1975)). Here, the 500-injections-over-six-years criterion was supported by the
opinion of Dr. Haller (whom, we note, Melgen was able to cross-examine). The 2,000-patient cutoff reflected Melgen’s own patient load. And the one-patient-each-year criterion matched Melgen’s own consistent practice during the relevant period. We therefore find no abuse of discretion in the district court’s decision to admit the charts under Rule 1006. Permitting the introduction of the underlying data under the business records exception to hearsay was also well within the district court’s discretion.

The Confrontation Clause did not apply to Melgen’s ability to cross-examine decisionmakers regarding the criteria that were used to make the summary charts. To begin with, the summaries were drawn from non-testimonial Medicare records that do not implicate the Confrontation Clause under *Crawford v. Washington*, 541 U.S. 36, 51 (2004). Melgen, however, argues that the mere act of choosing selection criteria to decide which doctors’ data to include in the summary comparisons was a testimonial act. He argues that he has the right to cross-examine whoever selected the criteria. Here, that would be the members of the prosecution team that directed the creation of the exhibit.

That approach has no basis in our law. Attorneys routinely make decisions about which evidence they believe is relevant to establishing a particular point—decisions that may include, for example, which witnesses to call, or as here, which

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2 For this reason, we also reject Melgen’s general hearsay argument raised in his initial brief—one which, as the government points out, was never made at trial, and so is reviewed for plain error. Melgen is correct that “Rule 1006 is not a back-door vehicle for the introduction of evidence which is otherwise inadmissible.” *Peat, Inc. v. Vanguard Research, Inc.*, 378 F.3d 1154, 1160 (11th Cir. 2004). But here the underlying Medicare data is admissible—so there is no concern that otherwise inadmissible testimony was snuck in as a summary.
summaries to enter into evidence. The Confrontation Clause “guarantees a criminal defendant ‘the right . . . to be confronted with the witnesses against him.’” *Al-Amin v. Warden*, 932 F.3d 1291, 1302 (11th Cir. 2019) (quoting U.S. Const. amend. VI). It does not reach back a step further to demand the opportunity to cross-examine an attorney over why they decided to call a particular witness—or, as in this case, about why they chose specific selection criteria in compiling the summary.

We note that Melgen did cross-examine the FBI analyst who presented the evidence, and questioned whether any errors might have been made in applying the chosen comparison criteria. The district court’s application of Rule 1006 therefore introduced no Confrontation Clause issue.

Melgen also argues that a sufficiently qualified expert under Rule 702 should have been required as a basis for entering the comparison charts. His argument on this point relies mainly on an unpublished district court decision from the Northern District of Illinois that declined to recognize two statisticians as experts because they were not experts in so-called medical statistics. *See United States v. Chhibber*, 741 F.3d 852, 854 (7th Cir. 2014) (describing the procedural history in the trial court but affirming the defendant’s conviction without addressing this issue). Whatever persuasive value that decision does or does not hold, we do not see the present case—where the district court had the testimony of medical experts on the rate of Lucentis injections that would indicate retinal practice specialty—as analogous. And as previously mentioned, the other
comparison criteria were reasonably supported by the evidence. We therefore affirm the district court’s admission of the summary charts.

IV.

We next address several of Melgen’s miscellaneous arguments concerning his trial. First, Melgen claims that the district court should have excluded any evidence of Melgen’s multi-dosing of Lucentis because the prosecution had ample other means for establishing Melgen’s profit motive. But we have already explained that through multi-dosing, Melgen could get reimbursed by Medicare at a rate of incredible profit, receiving up to three times the cost of obtaining the drug. That fact was probative of his profit motive for falsely diagnosing patients with wet ARMD and then prescribing Lucentis—whether or not his creativity in administering multiple doses of Lucentis from one vial was lawful. The district court did not err in admitting the evidence of multi-dosing.

Second, Melgen asks that we reverse the district court’s judgment because testimony from Delores Griffith (and her daughter) that Melgen never performed a particular surgery was later shown to be false. The district court denied Melgen’s motion for a mistrial on that basis.

Denial of a defendant’s request for a mistrial or new trial is reviewed for abuse of discretion. United States v. Vallejo, 297 F.3d 1154, 1163 (11th Cir. 2002). If the district court issued a curative instruction, this Court will reverse only if “the evidence is so highly prejudicial as to be incurable.” United States v. Dodd, 111 F.3d 867, 870 (11th Cir. 1997). At the time that the court became aware that the witness had testified incorrectly, the district court immediately
issued a thorough curative instruction. The objected-to witnesses’ testimony was not incurable—in fact, the district court ably explained to the jury that the witnesses had remembered falsely. Reversal is plainly not warranted.

Third, Melgen argues that the district court erred by declining to instruct the jury that the sample of patient files entered into evidence was not statistically random. As with the testimony from Delores Griffith, however, the court issued a curative instruction that avoided any prejudice on this point, telling the jury to disregard any statements concerning statistical confidence in the representative nature of the sample. That instruction was sufficient to avoid a mistrial.

Fourth, Melgen argues that the district court erred by providing the jury with twelve unredacted copies of the indictment—in particular, he argues that the court violated Federal Rule of Criminal Procedure 30(b). But that Rule only requires the court to notify the parties before closing arguments of “how it intends to rule on the requested instructions.” Fed. R. Crim. P. 30(b). Allowing the jury to receive twelve copies (rather than one) does not concern any ruling on the requested jury instructions—and thus does not implicate Rule 30(b).

Melgen does cite cases in which courts have warned that providing a copy of the indictment outlining the prosecution’s theory of the case may be unfairly prejudicial. But those cases are a far cry from this one. In one example, the judge had not given the jury any “neutral written jury instructions to guide them in their deliberations”—but did give them the indictment. *United States v. Van Dyke*, 14 F.3d 415, 423 (8th Cir. 1994). The potential for prejudice was obvious there; nothing comparable existed here. Moreover, because Melgen did not object when
he was informed that twelve copies of the indictment were sent to the jury—
instead saying “that’s fine”—any challenge to the number of copies given to the
jury would be reviewed for plain error, if at all. And Melgen identifies no
authority for concluding that the district court plainly erred by providing multiple
copies of the indictment. Nor can he establish any effect on his substantial rights,
as required to meet the standard for plain error, because the court repeatedly told
the jury that the indictment was not evidence of his guilt.

_Fifth_, Melgen argues that the district court erred by not asking more
questions or granting relief after learning of contact between a government witness
and two defense witnesses. Melgen asserts that the government witness
“intimidated” the defense witnesses. A district court’s decisions about whether to
grant a new trial and whether to conduct an evidentiary hearing regarding alleged
witness intimidation are reviewed for an abuse of discretion. _See United States v.
Perez-Oliveros_, 479 F.3d 779, 782 (11th Cir. 2007) (“We review the denial of a
motion for a new trial for abuse of discretion.”); _United States v. Arbolaez_, 450
F.3d 1283, 1293 (11th Cir. 2006) (“Generally, a court’s decision about whether to
hold an evidentiary hearing lies within that court’s sound discretion and will be
reviewed only for an abuse of discretion.”). After the district court learned of the
contact, the court conducted a brief hearing before deciding that the contacts had
not been prejudicial in the end because no testimony had been altered. Melgen
offers no explanation for how either witness’s testimony would have been
different, beyond the possibility that one witness’s demeanor slightly changed after
the contact. _Cf. United States v. Thompson_, 130 F.3d 676, 687 (5th Cir. 1997)
(“The defendant bears the burden of showing that testimony would have been different.”). The court did not abuse its discretion by concluding that no mistrial was required.

V.

Melgen also briefly challenges the sufficiency of the evidence supporting his convictions. “A jury’s verdict cannot be overturned if any reasonable construction of the evidence would have allowed the jury to find the defendant guilty.” United States v. Capers, 708 F.3d 1286, 1297 (11th Cir. 2013) (quoting United States v. Herrera, 931 F.2d 761, 762 (11th Cir. 1991)). On appeal, Melgen echoes the same argument he made to the jury—that the evidence supported a finding that any “mistakes” in diagnosing patients were not willfully false and that he reasonably believed the treatments were required. But the “evidence need not be inconsistent with every reasonable hypothesis except guilt, and the jury is free to choose between or among the reasonable conclusions to be drawn from the evidence presented at trial.” Id. (quoting United States v. Poole, 878 F.2d 1389, 1391 (11th Cir. 1989)).

That rule guides our conclusion that Melgen’s sufficiency of the evidence challenge fails. Melgen’s arguments go to the weight of the evidence, and not its sufficiency. The jury heard hours of evidence about Melgen’s motive and means for fraudulently billing Medicare for an expensive drug. It’s true that Melgen offered alternative explanations for some of the evidence against him; we are thinking, for example, of the claim that pre-prepping diagnoses before Melgen saw patients might have led to honest mistakes. But those explanations were for the
jury to weigh, not us. After all, the jury also could have seen pre-prepping as a sign of Melgen’s willful choice to treat the vast majority of his patients for ARMD, whether or not it was medically necessary. The scope of the scheme was easily enough for the jury to conclude that Melgen had engaged in systematic fraud, rather than committing isolated mistakes. We find the evidence sufficient to uphold the jury’s verdict.

And because the district court did not commit errors in its evaluation of the evidence, those non-errors cannot lead to the application of the cumulative error doctrine. We affirm Melgen’s conviction on all counts.

VI.

Before addressing Melgen’s sentence, we turn to his requests for a new trial under Brady and Federal Rule of Criminal Procedure 33. First, the Brady claim. Alleged Brady violations are reviewed de novo; it is the defendant’s burden to show all the elements of a violation. United States v. Jones, 601 F.3d 1247, 1266 (11th Cir. 2010). To succeed on his Brady argument, Melgen must show that (1) the government possessed evidence favorable to him; (2) he did not possess the evidence and could not obtain the evidence with any reasonable diligence; (3) the prosecution suppressed the favorable evidence; and (4) had the evidence been disclosed to him, there is a reasonable probability that the outcome would have been different. Vallejo, 297 F.3d at 1164.

In denying Melgen’s motion for a new trial on this basis, the district court explained that the “information upon which Defendant relies was not newly discovered, and assuming it was, it probably would not have changed the outcome
of the trial.” We agree. The main piece of purported *Brady* evidence was a statement that a witness for the government, Dr. Berger, made during sentencing.³ The content of the statement was the medical fact that the use of an anti-VEGF drug could control leakage of wet ARMD, hiding signs of the disease. That is not the kind of evidence that could not have been obtained before trial—it is medical testimony that Melgen could have introduced himself with a variety of medical witnesses. Perhaps recognizing that fact, Melgen claims that the new evidence is not the contention itself but that one of the government’s witnesses agreed with the contention. But this inappropriately focuses on the *who*, rather than the *what*, of the testimony—which does not satisfy *Brady*’s requirement that the evidence be unobtainable without reasonable diligence. Melgen could have asked any of the government’s witnesses if they agreed with that point during trial, or called his own witnesses. Really, the mere fact that a particular government witness agreed with a fact that Melgen finds useful to his defense is not “new evidence.” Nor is it likely, in light of all the evidence, that Berger’s opinion would have changed the outcome at trial.

Melgen also asked for a new trial under Rule 33. But relief under that Rule cannot be predicated on supposed new evidence that merely is impeaching. *United States v. DiBernardo*, 880 F.2d 1216, 1224 (11th Cir. 1989). The district court did not err in denying Melgen’s motion for a new trial under Rule 33 because the

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³ Melgen possessed another piece of purported *Brady* evidence, an internal e-mail from within CMS, before trial began—which automatically defeats his *Brady* claim. *See Felker v. Thomas*, 52 F.3d 907, 910 (11th Cir. 1995) (no *Brady* violation where the defendant knows or should have known of the allegedly exculpatory information before trial).
“new” evidence was merely evidence that might, at best, have been used as weak impeachment evidence against the government’s witnesses.

VII.

Melgen next appeals his sentence as procedurally and substantively unreasonable. We review the reasonableness of a sentence under an abuse-of-discretion standard. United States v. Irey, 612 F.3d 1160, 1188–89 (11th Cir. 2010) (en banc). In reviewing a sentence for reasonableness, we first consider whether the district court committed any significant procedural error, and next consider whether the sentence was substantively reasonable. Gall v. United States, 552 U.S. 38, 51 (2007). The party challenging the sentence bears the burden to show that the sentence is unreasonable considering the record and the § 3553(a) factors. United States v. Tome, 611 F.3d 1371, 1378 (11th Cir. 2010). Those factors include the need to reflect the seriousness of the offense, promote respect for the law, provide just punishment for the offense, deter criminal conduct, and protect the public from the defendant’s future criminal conduct. See 18 U.S.C. § 3553(a)(2). After evaluating for reasonableness, we will only vacate a defendant’s sentence if left with the firm conviction that the district court committed clear error in weighing the § 3553(a) factors and imposing a sentence outside the range of reasonable sentences based on the facts. Irey, 612 F.3d at 1190.

Here, the district court did not commit procedural error in determining Melgen’s sentence. Melgen’s procedural challenge hinges on several determinations that went into the district court’s loss calculation. We review a
district court’s determination of the loss amount under the Sentencing Guidelines for clear error. *United States v. Baldwin*, 774 F.3d 711, 727 (11th Cir. 2014). We will conclude that a finding of fact is clearly erroneous only we are “left with a definite and firm conviction that a mistake has been committed.” *United States v. Pierre*, 825 F.3d 1183, 1191 (11th Cir. 2016) (quoting *United States v. Rothenberg*, 610 F.3d 621, 624 (11th Cir. 2010)). Because the district court is in a unique position to assess the evidence and estimate the loss based upon that evidence, its loss determination is entitled to appropriate deference.

U.S.S.G. § 2B1.1 cmt. n.3(C). The Sentencing Guidelines define “loss” as the greater of “actual” loss or “intended” loss. *Id.* § 2B1.1 cmt. n.3(A). “Actual loss” is defined as the reasonably foreseeable pecuniary harm that resulted from the offense, and “intended loss” is defined as the pecuniary harm that was intended to result from the offense, including pecuniary harm that would have been impossible or unlikely to occur. *Id.* Losses that insurance companies and patients sustain that result from Medicare fraud are “relevant conduct that may be considered by the district court when calculating the amount of loss.” *Hoffman-Vaile*, 568 F.3d at 1344.

Here, the district court did not clearly err in calculating the loss amount. The government presented enough evidence that the sample patient group was sufficiently representative of Melgen’s patient population between 2010 and 2012 for the district court to make a reasonable estimate based on that sample. And those years are only a portion of the timeframe covering Melgen’s scheme—suggesting that he surely obtained even more Medicare funds than the district court
accounted for. Melgen’s expert witness conceded that, while the government was missing the “seed” number that was used by a computer program to generate that sample, there was no reason to question the functionality of that program. The district court was also entitled to consider both the 80% of treatment cost that Medicare ordinarily pays as well as the 20% that has to be covered by other payment sources. *Id.* at 1343–44.

Finally, the district court did not clearly err in reaching its final loss determination, despite Melgen’s argument that some patients in fact had diseases that required treatments for which Medicare would have offered some degree of reimbursement. Again, the district court need only reach a reasonable estimate of loss. Under the commentary to the Guidelines, when a defendant is convicted of a federal healthcare offense involving a government healthcare program, the aggregate dollar amount of fraudulent bills constitutes prima facie evidence of the amount of the intended loss, if not rebutted. U.S.S.G. § 2B1.1 cmt. n.3(F)(viii). The district court did not err in concluding that Melgen had failed to rebut the prima facie evidence of loss.⁴ As the court stated, the “mere fact that Defendant’s treatment could have possibly benefitted another condition his patients may have had, but which he did not indicate he was treating, is insufficient to rebut the government’s proof. It is pure speculation that any of Defendant’s patients who were improperly diagnosed and treated for conditions that they did not have actually benefitted from the treatments they did receive.” *Cf. United States v.*

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⁴ For similar reasons, we reject Melgen’s brief suggestion that the district court clearly erred by declining to consider amounts that he may have repaid during the civil multi-dosing litigation.
Dehaan, 896 F.3d 798, 808 (7th Cir. 2018) (treating amounts paid by Medicare to a fraudulent provider as a loss even though some of the physician’s patients may have qualified for treatment).

Nor was Melgen’s (below-Guidelines) sentence substantively unreasonable. In considering the substantive reasonableness of a sentence, we consider the totality of the circumstances and whether the sentence achieves the sentencing purposes stated in § 3553(a) and described above. United States v. Sarras, 575 F.3d 1191, 1219 (11th Cir. 2009). “A district court’s sentence need not be the most appropriate one, it need only be a reasonable one.” Irey, 612 F.3d at 1191. Here, the court expressly considered Melgen’s “age,” his “lack of criminal history,” and his “medical conditions” before concluding that Melgen deserved a downward variance to 204 months but no further. In light of the extent of Melgen’s fraudulent scheme, the sentence the district court imposed was more than reasonable.

AFFIRMED.
18th Annual Healthcare Law Compliance Symposium

Session 2: **Key Issues in Peer Review**

- Nick Jurkowitz, Fenton Law Group
- David Balfour, Buchalter
Wading into Peer Review

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David Balfour is a Shareholder in the Firm’s San Diego office, and a member of the Healthcare practice group. Mr. Balfour brings two decades of experience to his practice, representing clients in the healthcare sector on a wide range of issues including medical staff peer review proceedings, licensing proceedings, writ proceedings, State and Federal Court civil litigation, and related appellate proceedings. He represents hospitals, health systems, medical staffs, medical groups, and individual healthcare providers regarding litigation risks and best practices to avoid litigation exposure.

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Nick Jurkowitz has a wide range of experience representing and advising healthcare providers on litigation and regulatory related matters. He has represented providers in all aspects of administrative hearings and investigations, including hospital peer review proceedings. He regularly counsels clients on navigating the complex state and federal healthcare regulatory requirements.
What is Peer Review?

Defined under Bus & Prof Code §805

“Peer review” is “a process in which a peer review body reviews the basic qualifications, staff privileges, employment, medical outcomes, or professional conduct of licentiates to make recommendations for quality improvement and education” in order to assess the competency or continued competency of its members.

Can mean both an informal and formal process.
Purpose of Peer Review

Peer review is the process by which a committee comprised of licensed medical personnel at a hospital "evaluate[s] physicians applying for staff privileges, establish[es] standards and procedures for patient care, assess[es] the performance of physicians currently on staff," and reviews other matters critical to the hospital's functioning.

*Arnett v. Dal Cielo* (1996) 14 Cal.4th 4, 10
Higher Purpose of Peer Review

Peer review serves a hospital's self-interest: For example, a hospital may remove a physician from its staff as a means to reduce its exposure to possible malpractice liability. But peer review of physicians also serves an important public interest. Hospital peer review, in the words of the Legislature, "is essential to preserving the highest standards of medical practice" throughout California. (Bus. Prof. Code, § 809, subd. (a)(3).)
Benefits and Dangers of Peer Review

Peer review, fairly conducted, is essential to preserving the highest standards of medical practice.

Peer review that is not conducted fairly results in harm to both patients and healing arts practitioners by limiting access to care.

• Bus. & Prof. Code 809
Who is Subject to Peer Review?

A professional medical staff of licensed facilities under Division 2 of the Health & Safety Code

Ambulatory Surgery Centers that are certified to participate in the federal Medicare program

Some health care service plans

Certain professional medical societies that have 25 or more members (e.g. medical, psychological, dental organizations)

A committee organized by an entity employing or consisting of more than 25 licentiates

Bus. & Prof Code 805(a)(1)(B)
Medical Staff of Acute Care Hospital

• A medical or professional staff of any health care facility or clinic licensed under Health & Safety Code section 1200 et seq.

• A medical staff is self-governing under Bus. & Prof. Code §2282.5, which includes right to select leaders, make Bylaws & rules, establish standards, oversee quality

• Medical Staff interdependent with Hospital; Hospital Governing Body is ultimate authority

• Medical Staff elected leaders -- Department Chairs, At Large Members -- make up Medical Executive Committee. Chair of MEC is Chief of Staff
Ambulatory Surgery Centers

Especially in small physician-owned surgery centers:
May be difficult/unreliable to do peer review because of broad range of unrelated specialists (podiatry; GI; ophthalmology);
Business Interests, such as Safe Harbors, may cause other owners to be resistant to restricting physician-owner privileges;
Beware exercise of corporate powers in disregard of MD fair procedure rights
Medical Groups
Employment Decisions v. Peer Review Decisions

Ownership/Partnership Rights v. Peer Review Fair Procedure Rights

Beware Closed Department/Economy situation where Hospital/Medical Staff demands medical group remove physician from practice at hospital
Health Plans

Increasing efforts/sophisticated scrutiny of health plans in auditing (identify outliers)

Determinations based upon need/utilization

No hearing rights if plan delistment based upon action taken by other peer review body
Statutory Authority & Bylaws

• In California, the peer review/corrective action system is governed by Business & Professions Code section 800 et. seq.
  • 805 – Peer Review defined, Reporting on Corrective Actions
    • 801/802 – Malpractice Reports
    • 809 – Hearing Rights

• Hospitals and Medical Staffs each have their own Bylaws

• Hospitals are accredited by The Joint Commission, formerly the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO). Accreditation is key to getting/maintaining eligibility for Medicare funding
Investigation

Routine monitoring of every physician’s performance must be done (e.g. complication rates; infection rates; blood loss; H & P’s completed timely, etc)

Investigation looks at the performance or conduct of an individual physician. An investigation must proceed any corrective action.
Corrective Action and Medical Disciplinary Cause or Reason

• “Corrective action” refers to a restriction, reduction or termination of a physician’s clinical privileges. Corrective action taken for a medical disciplinary cause or reason is reportable to the Medical Board of California.

• "Medical disciplinary cause or reason" as defined in 805(a)(6) means that aspect of a licentiate's competence or professional conduct that is reasonably likely to be detrimental to patient safety or to the delivery of patient care.
Consequences of Peer Review

- **Informal**
  - Verbal Warning
  - Written Warning/Reprimand
  - Mandated Classes/Coursework
  - Referral to Well-Being Committee
  - Behavioral Contract

- **Formal**
  - Closure of Investigation w/o Action
  - Reduction/restriction in Privileges (scope of what permitted to perform)
  - Suspension of Privileges
  - Termination of Privileges
  - Imposition of Other Conditions on Privileges
805 Reports

The report required to be filed by a peer review body to the California Medical Board under certain circumstances:

Staff membership application is denied for medical disciplinary reasons
Privileges are terminated or revoked for medical disciplinary cause or reason
Resignations or withdrawals of application while an investigation is pending for medical disciplinary cause or reason
A suspension that lasts in excess of 14 days
Restrictions are imposed for a cumulative total of 30 days over a 12 month period
Must be filed within 15 days after the effective date
805.01 Reports

Based upon a final decision after formal investigation
Report is due 15 days after decision is made. A medical staff need not suspend a physician in order for the report to be required
Monetary Penalties for non-compliance

Decisions that require the report:
Incompetence, gross negligence, repeated deviation from standard of care involving death or serious bodily injury to one or more patients
Abuse/ self-prescribing of controlled substances or dangerous drugs
Excessive prescriptions of controlled substances
Sexual misconduct with a patient
What rights is a physician entitled to if a peer review body takes any action for which an 805 report must be filed?

A physician is entitled to the fair procedure rights of Notice and a Hearing.
Hearing Provisions-
Bylaws

Parties are bound by any additional notice and hearing provisions contained in any applicable professional society, medical staff bylaws, contract or agreement, which are not inconsistent with Sections 809.1 - 809.4.
Statutory Hearing Provisions are Not Waivable

The provisions of Sections 809.1 to 809.4 (Hearing rights provisions) may not be waived in any instrument for a final proposed action for which a report is required to be filed under Section 805.
Notice Provisions

• Required after a “final proposed action” defined as the final action or recommendation made by a peer review body
• Under Bus. & Prof. Code § 809.1 Notice must include:
  • Action has been proposed that if adopted an 805 report will be filed
  • The final proposed action (e.g. restrictions being placed or termination of privileges)
  • Licentiate is entitled to a hearing
  • The time limit for which the licentiate must request a hearing (usually 15 or 30 days)
  • In the case of a summary suspension, the licentiate may be suspended first and then “subsequently” be provided the notice rights under 809.1
Hearing

How the hearing process generally works—evidentiary trial

• Hearing officer
  • Makes evidentiary rulings, writes Decisions based on JRC Decision
• Judicial Review Committee
  • Acts as the jury
• Evidence
  • Witnesses
    • Expert testimony
  • Exhibits
• Panel involvement
  • Can ask questions; Generally can request documents and additional review of relevant information even if not a marked exhibit by either part
Hearing Process

• Can be very costly
• Generally from investigation to conclusion of hearing can take months and sometimes longer than a year
• Hearings usually occur at night to accommodate physician’s schedules
• Hard to coordinate days so generally only a few sessions a month
• Having an arbitrator only and no physician hearing panel can speed the process up
• Time limit to request a hearing
• Bylaws dictate the time frame when a hearing must be requested, which is usually 30 days but varies
• Right to voir dire the hearing officer and the panel members
• Bias usually focuses on an actual bias or financial bias
Appeal Rights

**Internal administrative remedies:**
Must exhaust, appeal to hospital governing board
Bylaws dictate standard and sometimes can exercise independent review
What to do with partial victory?

**CCP §1094.5 Writ of Mandate**
Petitioner must persuade court by preponderance of the evidence that the review board decision is not supported by the weight of the evidence
Peer review and Retaliation Lawsuits

- Statutory law protects physicians from retaliation for advocating for patient safety
  - Health & Safety Code §1278.5; Bus. & Prof. Code § 2056
  - Includes actions of suspending or terminating privileges
- Exception to exhaustion requirement
- ANTI-SLAPP Considerations
  - Claims based upon protected speech v. actions that result
Immunities

Peer review bodies and individual members participating in the peer review process enjoy various privileges.

Civil Code 43.7(b)

Immunity for individual members of a medical staff for actions and decisions undertaken within the scope of functions of the committee as long as action undertaken without malice.

Civil Code 43.8(a)

Protects communications between medical staff and other interested entities when the communication is necessary to evaluate the physician as an applicant or member.

42 USC 11112/ HCQIA

Federal law also protects hospitals and peer reviewers from liability for actions taken, as long as the actions are fair and reasonable.
Protecting colleagues against anti-competitive behavior

Speak up in committee meetings if you see something unfair

Avoid investigations that are conducted by or spearheaded by competitors

Establish fair procedures for bringing cases to peer review and how they will be reviewed from there

Transparency: Let the physician know he or she is being investigated in the beginning to address any potential bias
Confidentiality
Evidence Code 1157: Protect peer review documents and information from being produced in discovery in certain situations.

Peer Review is a process designed to promote candor with the dual aims of improving the performance by physicians and improving the quality of care received by patients.