

Compliance, and Enforcement In the COVID-19 Era

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The COVID-19 Pandemic

New Sources of Federal Funding

- Coronavirus Preparedness and Response Supplemental Appropriations Act
- Families First Coronavirus Response Act
- Coronavirus Aid, Relief, and Economic Security (CARES) Act
- Paycheck Protection Program and Health Care Enhancement (PPP/HCE) Act
- Consolidated Appropriations Act of 2021

Government Focus on Fraud

“Every U.S. Attorney’s Office is hereby directed to prioritize the detection, investigation, and prosecution of all criminal conduct related to the current pandemic.”

– Attorney General William Barr

“Attorney General William P. Barr is urging the public to report suspected fraud schemes related to COVID-19 . . . Some examples of these schemes include . . . Medical providers obtaining patient information for COVID-19 testing and then using that information to fraudulently bill for other tests and procedures.”

- DOJ Press Release

Enforcement and Recoveries in 2020

2020 Activity

- DOJ recovered more than \$2.2 billion in FY 2020 under the FCA
 - Nearly \$1 billion less than last year
 - 12th year of recoveries exceeding \$2 billion
- Of \$2.2 billion –
 - \$1.8 billion from healthcare industry
 - \$1.7 billion related to cases filed by whistleblowers
- 672 new *qui tam* cases filed
 - Average of 13 new cases per week
 - Way up from 1987's 30 per year
 - Whistleblowers received over \$309 million

Notable Settlements

- *Settlements related to opioid crisis:*
 - \$2.8 billion settlement with Purdue Pharma LP re: allegations it promoted its opioid drugs to providers despite knowing providers were prescribing opioids for unsafe, ineffective, and medically unnecessary uses.
 - \$300 million settlement with Indivior re: allegations it promoted medically unnecessary use of opioid-addiction-treatment drug and provided misleading information about its benefits.

Notable Settlements

- *First False Claims Act relating to CARES Act*
 - President and CEO settle for \$100,000 for making false statements for PPP loans
 - <https://www.justice.gov/usao-edca/pr/eastern-district-california-obtains-nation-s-first-civil-settlement-fraud-cares-act>
- *Using charities to subsidize patients' copays:*
 - \$642 million settlement re: allegations it illegally used three charitable foundations as conduits to pay copayments of Medicare patients taking drugs sold by the company to treat multiple sclerosis and cancer.
 - \$97 million settlement re: allegations it illegally used a charitable foundation as a conduit to pay copayments of Medicare patients taking a drug sold by the company to treat pulmonary arterial hypertension.

Enforcement Trends

- Telehealth regulations relaxed during pandemic, but telehealth fraud remains an enforcement focus
- Focus on Medicare Advantage plans and long-term care facilities under CARES Act
- Expansive reading of illegal kickbacks
- Parallel proceedings
- Declined cases continued by whistleblowers
- Continued focus on individual accountability

Personal Protective Equipment (PPE) Fraud

- The Attorney General in March directed all U.S. Attorney's Offices to prioritize the detection, investigation and prosecution of criminal conduct related to the pandemic through COVID Fraud Coordinators in each office. Many also established state/regional task forces.
- The President issued an Executive Order also in March invoking the Defense Production Act of 1950 (DPA) which focus on production, anti-hoarding, and fair pricing of PPE.
- The Attorney General in March formed the DOJ Hoarding & Price Gouging Task Force, which is a nationwide effort to deter, detect, and prosecute hoarding and profiteering in the sale of PPE essential to combatting spread of COVID-19.
- By October the NCDF received more than 76,000 tips concerning COVID-related wrongdoing.
- The FBI's Internet Crime Complaint Center has also received more than 20,000 tips regarding suspicious websites and media postings.

PPE Fraud – cont'd.

- Under the authority of the Defense Production Act (DPA), DOJ's Task Force seized in March 2020 approximately *192,000 N95 respirator masks* *598,000 medical grade gloves* and *130,000 surgical masks*, procedure masks, N100 masks, surgical gowns, disinfectant towels, particulate filters, bottles of hand sanitizer, and bottles of spray disinfectant.
 - Is a criminal statute
- HHS reported that it would pay the owner of the hoarded equipment pre-COVID-19 FMV for the supplies and has begun distributing to meet the critical need for the supplies among healthcare workers in New York and New Jersey

Payroll Protection Program (PPP) Fraud

- The CARES Act is a federal law enacted March 29, 2020 to provide emergency financial assistance Americans suffering economic effects resulting from the COVID-19 pandemic.
- CARES Act authorized \$349 billion in forgivable loans to small businesses. In April 2020, Congress authorized over \$300 billion in additional PPP funding.
- PPP allowed qualifying organizations to receive loans with a maturity of two years and an interest rate of one percent. Businesses were required to use PPP loan proceeds for payroll costs, interest on mortgages, rent and utilities.
- PPP allows interest and principal to be forgiven if businesses spent funds on these expenses within a set time period and use at least a certain percentage of the loan towards payroll expenses.
- PPP loan amount depended on the number of employees employed by the business and the business's average monthly payroll costs.

PPP Risks

- When applying for funds under the program, an “Authorized Applicant” expressly verified that the following statement was true:

“Current economic uncertainty makes this loan request necessary to support the ongoing operations of the applicant.”

- Neither the statute nor the SBA guidance provides detailed instructions on what this statement means.
- Typical Mistakes -
 - PPP funds used for unauthorized purpose (*i.e.* something other than payroll costs, mortgages, rent and utilities).
 - A recipient overstated payroll costs, number of employees or other allowable expenses.
- In April 2020, the Treasury Secretary reported:

“...any loan over \$2 million, the SBA will be doing a full review of that loan before there is loan forgiveness”

PPP Risks, cont'd.

Effective compliance includes –

- Documenting how current economic uncertainty impacted the provider's financial situation in terms of revenues and expenses.
- Describe how COVID impacted the new referrals to your organization from its traditional referral base (such as physician practices, hospitals, etc.). Based on these changes to provider's referral base, what level of economic uncertainty is facing the company?
- Has COVID altered your ability to maintain adequate staffing to care for patients or has workload changed? If so, how?
- What steps did you take to make sure that PPP funds are properly utilized?
- How did COVID situation has impacted your organization's ability to retain and pay its employees. Was there a hiring freeze, layoffs or salary cuts?
- If no loan, what affect would have happened, or would there be an organization at all?

PPP Fraud, cont'd.

- False Claims Act, 31 U.S.C. §§ 3729-33
- Wire Fraud, 18 USC § 1343
- Conspiracy to Commit Bank Fraud, 18 USC § 1349
- Bank Fraud, 18 USC § 1344
- Money Laundering, 18 USC § 1957
- False Statements to Influence the SBA, 15 USC § 645(a)
- Aggravated Identity Theft, 18 USC § 1028A
- Forfeiture, 18 USC § 981(a)(1)(C); 28 USC § 2461(c)

Provider Relief Funds

- Provider Relief Funds intended to support healthcare-related expenses or lost revenue attributable to COVID and help ensure continued treatment for COVID.
- Terms and Conditions require recipients be able to demonstrate lost revenues and increased expenses attributable to COVID, excluding other sources.
- Must attest to accuracy of submission and to provide data to demonstrate losses/expenses arising from COVID.

Recipient certifies that it billed Medicare in 2019; provides or provided after January 31, 2020 diagnoses, testing, or care for individuals with possible or actual cases of COVID-19;... The Recipient certifies that the Payment will only be used to prevent, prepare for, and respond to coronavirus, and that the Payment shall reimburse the Recipient only for health care related expenses or lost revenues that are attributable to coronavirus.”

- Funds must be expended no later than June 30, 2021.

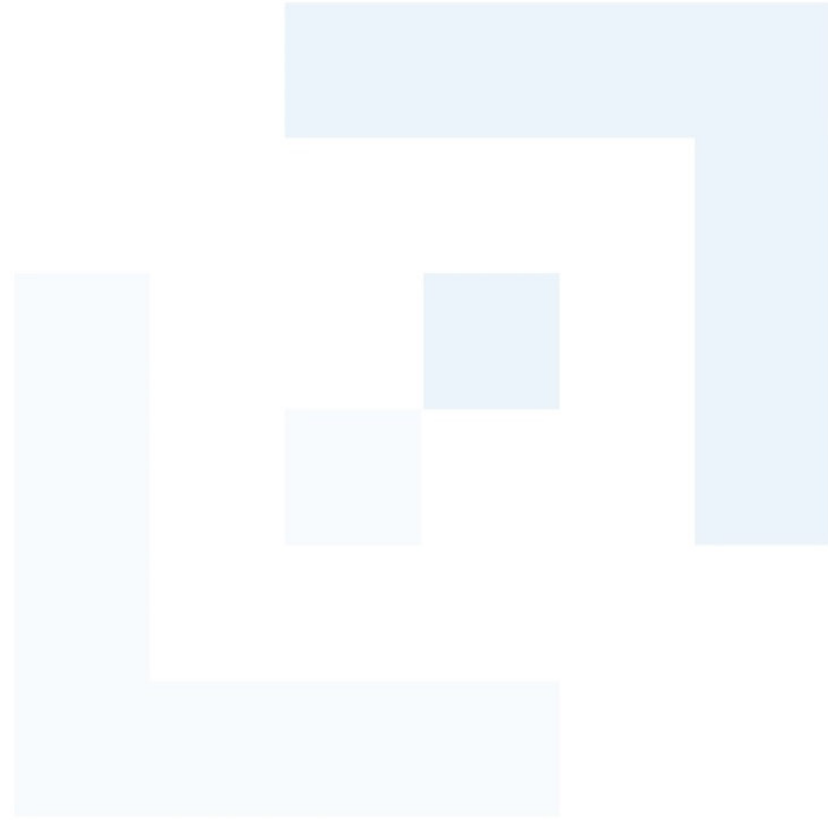
Relief Funds, cont'd.

- HHS states “if a recipient does not have lost revenues or increased expenses due to COVID-19 equal to the amount received a recipient must return the funds.”
- If payroll shortfalls are covered by a PPP loan, then losses do not justify keeping a distribution of Provider Relief Funds (and vice versa).
- Expected that OIG-HHS will provide significant audit and oversight ensuring appropriate use of funds and if any overpayment exists,

Outlook for 2021

- Greater FCA recoveries under “old” theories and “new” CARES Act.
- CARES Act criminal enforcement.
- Individual civil and criminal liability.
- Telehealth fraud enforcement and Opioid crisis continue.
- Uncertain regulatory environment (new administration held up AKS/Stark and other regulations).
- Increased OSHA and HIPAA/data breach penalties (both enforcement and private).

Questions



Thank You



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Sean McKenna solves clients' healthcare needs and represents companies, clinicians, and executives in white collar cases and civil FCA investigations.

As a former ten-year Assistant United States Attorney, Associate Counsel to the Inspector General, and General Counsel for the U.S. Department of Health and Human Services, Sean is a nationally recognized healthcare attorney who focuses his practice on matters involving the health care industry. His work includes assisting clients with internal investigations and compliance reviews, as well as advising on them state and federal fraud and abuse rules. He is a frequent invited speaker at national, regional, and local conferences.

Sean has been a leader in the ABA's Health Law Section since 2013 and was a member of the State Bar of Texas's Health Law Section Council from 2013–2018.