Legal and Regulatory Update

HCCA Virtual Orange County Regional Healthcare Compliance Conference

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KING & SPALDING

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Agenda

- Snapshot of the Enforcement and Compliance Landscape
- Overview of Important Legal and Regulatory Developments
- COVID-19 Legislative and Regulatory Changes
- Enforcement Areas of Focus
- Key Takeaways and Compliance Strategies

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Snapshot of the Enforcement and Compliance Landscape

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FCA Enforcement

The False Claims Act (FCA) continues to be the government's fraud enforcement tool of choice.

- In Fiscal Year 2019, DOJ recovered ***over $3 billion*** in settlements and judgments in civil cases involving fraud and false claims against the government.
  - Compared to ***over $2.8 billion*** in Fiscal Year 2018.
- Of the over $3 billion in recoveries, **$2.6 billion** related to healthcare industry matters.
- 2019 was the 10th consecutive year that DOJ's civil healthcare fraud settlements and judgments have exceeded $2 billion.

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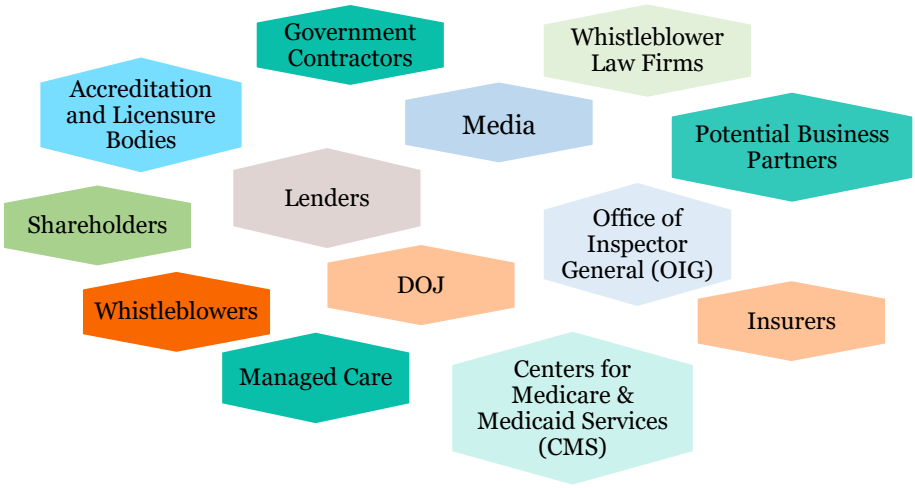
Expanding Universe of Evaluators



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Individual Accountability

Enforcement focus on individual accountability continues.

- DOJ revised certain Yates Memo policies to focus more specifically on senior leadership.
- General focus on individual accountability remains the same.

> "[A] company must identify all wrongdoing by senior officials, ***including members of senior management or the board of directors***, if it wants to earn any credit for cooperating in a civil case."
>
> - Former Deputy Attorney General Rod J. Rosenstein, American Conference Institute's 35th International Conference on the Foreign Corrupt Practices Act (Nov. 29, 2018)

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Compliance Program Effectiveness Focus Continues in 2020

Expectations for compliance programs continue to increase:

- Recent years have seen numerous issuances from DOJ and OIG regarding expectations for compliance programs.
  - DOJ released updated guidelines regarding evaluating corporate compliance programs on **June 1, 2020.**
- There is an emphasis on the ability to proactively identify and mitigate risk.
  - Failure to proactively identify, assess, and remediate risks increases chances for government investigations and whistleblower suits.

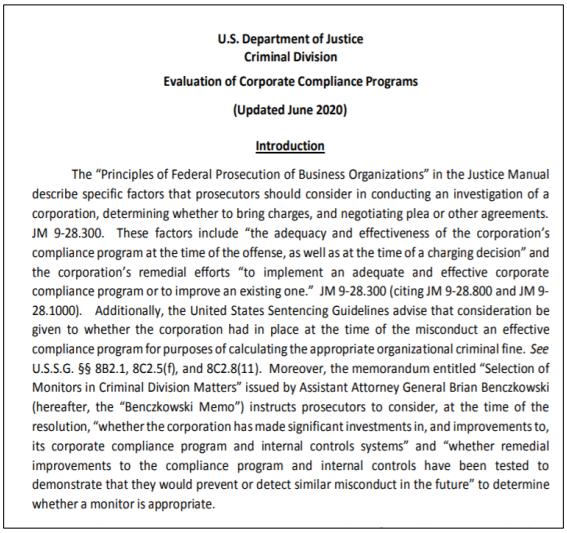
Updated DOJ Guidelines For Evaluating Compliance Programs

Updated DOJ guidelines on compliance programs build upon longstanding themes regarding the agency's approach to compliance program effectiveness.

- The guidelines were originally released in February 2017 and were also updated April 2019.
- The June 2020 DOJ Compliance Guidance largely resembles the prior version released in April 2019.
- The mere pace of the updates from DOJ underscores DOJ's focus on compliance program effectiveness.

Updated DOJ Guidelines For Evaluating Compliance Programs

- DOJ compliance program guidance is structured around three "fundamental questions:"
  1. *Is the corporation's compliance program* ***well designed****?*
  2. *Is the program being* ***applied earnestly and in good faith****? In other words, is the program* ***adequately resourced*** *and* ***empowered*** *to function effectively?*
  3. *Does the corporation's compliance* ***program work in practice****?*



U.S. Department of Justice
Criminal Division

Evaluation of Corporate Compliance Programs

(Updated June 2020)

Introduction

The "Principles of Federal Prosecution of Business Organizations" in the Justice Manual describe specific factors that prosecutors should consider in conducting an investigation of a corporation, determining whether to bring charges, and negotiating plea or other agreements. JM 9-28.300. These factors include "the adequacy and effectiveness of the corporation's compliance program at the time of the offense, as well as at the time of a charging decision" and the corporation's remedial efforts "to implement an adequate and effective corporate compliance program or to improve an existing one." JM 9-28.300 (citing JM 9-28.800 and JM 9-28.1000). Additionally, the United States Sentencing Guidelines advise that consideration be given to whether the corporation had in place at the time of the misconduct an effective compliance program for purposes of calculating the appropriate organizational criminal fine. *See* U.S.S.G. §§ 8B2.1, 8C2.5(f), and 8C2.8(11). Moreover, the memorandum entitled "Selection of Monitors in Criminal Division Matters" issued by Assistant Attorney General Brian Benczkowski (hereafter, the "Benczkowski Memo") instructs prosecutors to consider, at the time of the resolution, "whether the corporation has made significant investments in, and improvements to, its corporate compliance program and internal controls systems" and "whether remedial improvements to the compliance program and internal controls have been tested to demonstrate that they would prevent or detect similar misconduct in the future" to determine whether a monitor is appropriate.

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Intersection with the FCA

"… a compliance system that the company circumvents or does not adhere to could be highly relevant evidence that the company recklessly disregarded the law in violation of the False Claims Act. On the other hand, ***a robust compliance program that the company does follow and that identifies potential problems that are timely addressed by the company could demonstrate good faith and lack of scienter or otherwise be a strong mitigating factor in the government's assessment of liability.***"

— Principal Deputy Associate Attorney General Claire McCusker Murray (May 2019)

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Overview of Important Legal and Regulatory Developments

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Proposed Stark Law & Anti-Kickback Statute Changes

- October 19, 2019: CMS and OIG released proposed changes to the Stark Law, Anti-Kickback Statute safe harbors, and the beneficiary inducements provision in the civil monetary penalties law (the Beneficiary Inducement CMP).
- December 31, 2019: Comments to the proposed changes were due.

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Proposed Stark Law Changes

"The **Stark Law's new value-based exceptions**, under the proposed rule issued by the Centers for Medicare & Medicaid Services (CMS), **acknowledge that incentives are different in a healthcare system that pays for value, rather than the volume, of services provided**. They include proper safeguards that ensure the Stark Law will continue to provide **meaningful protection against overutilization and other harms, while giving physicians and other healthcare providers added flexibility** to improve the quality of care for their patients."

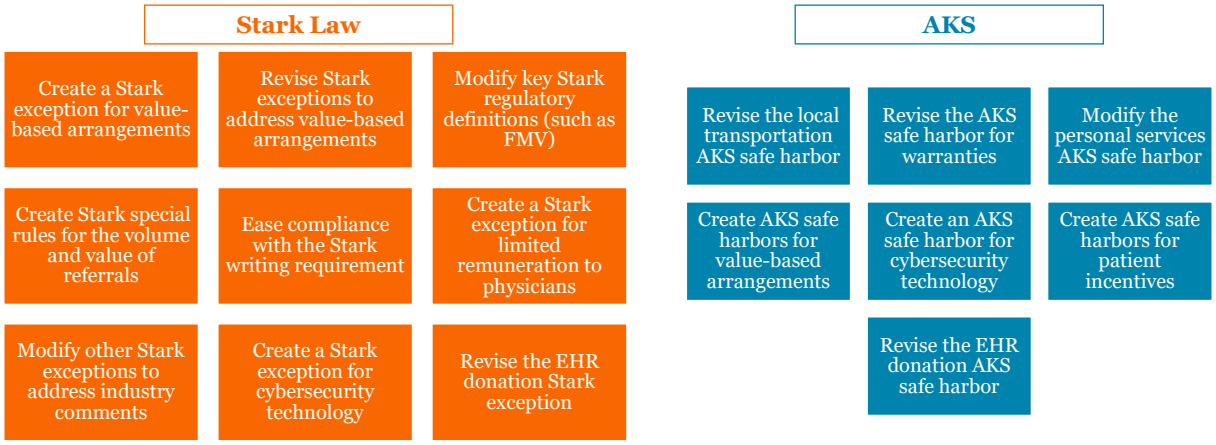
– HHS Press Release, on the release of the proposed changes (emphasis added)

Proposed Anti-Kickback Statute Changes

"The proposed changes to the regulations related to the **Federal Anti-Kickback Statute and the Civil Monetary Penalties Law** issued by the Office of Inspector General (OIG) would, if finalized, **address the longstanding concern these laws unnecessarily limit the ways in which healthcare providers can coordinate care for patients**. The changes would offer **flexibility for beneficial innovation and improved coordinated care** through, for example, outcome-based payment arrangements that reward improvements in patient health. The changes would also make it easier for physicians and other healthcare providers to ensure they are complying with the law by **offering specific safe harbors for these arrangements**."

– HHS Press Release, on the release of the proposed changes (emphasis added)

Proposed Stark Law & Anti-Kickback Statute Changes



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AseraCare

Eleventh Circuit decision raises standard for government to prove falsity in FCA cases, but demonstrates need for strong internal compliance.

- In *AseraCare*, the government alleged that defendants relied on erroneous clinical judgments in deeming patients terminally ill and made false claims for corresponding hospice reimbursements under Medicare.
- In its September 9, 2019 opinion, the 11th Circuit held that a clinical judgment cannot be the basis of an FCA claim unless the government can prove it was objectively false.
- For example, if a physician declares a patient terminally ill without reviewing relevant medical documentation or otherwise assessing the patient's condition, then that clinical judgment would be objectively false.
- *AseraCare* demonstrates the need for companies to implement procedures to ensure its certifications are clinically sound and sufficiently documented.

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Price Transparency Final Rule

- The Price Transparency Final Rule applies to nearly all **hospitals** operating in the United States.
- The Final Rule takes effect on **January 1, 2021.**
- Requires hospitals to:
  - Make public a machine-readable file online that includes **all standard charges** for all hospital items and services.
  - Make public specific charges for at least 300 **"shoppable" services** that are displayed and packaged in a consumer-friendly manner.

Price Transparency Final Rule

Hospitals will be monitored for noncompliance.

- Monitoring and enforcement will be based on third-party complaints.
- Noncompliance may result in:
  - CMS audits;
  - Corrective action plans; and/or
  - Penalties.

Skilled Nursing Facilities (SNF) Enforcement

- March 3, 2020: DOJ launched the National Nursing Home Initiative.
  - Coordinated effort by DOJ's Elder Justice Initiative and U.S. Attorneys' Offices.
    - Elder Justice Initiative: coordinates DOJ's activities combating elder abuse, neglect and financial exploitation, especially as they impact federal healthcare programs beneficiaries.
- Goal: coordinate and enhance **civil and criminal efforts to pursue nursing homes** that provide grossly substandard care to their residents.

"Millions of seniors count on nursing homes to provide them with quality care, and to treat them with dignity and respect when they are most vulnerable. Yet, all too often, we have found nursing home owners or operators who put profits over patients, leading to instances of gross abuse and neglect. This national initiative will **bring to justice those owners and operators who have profited at the expense of their residents**, and help to **ensure residents receive the care to which they are entitled**."

—Attorney General Bill Barr, in March 3, 2020 DOJ Press Release announcing the Initiative

SNF Enforcement

- Considers factors including:
  - Failure to provide adequate nursing home staff;
  - Failure to adhere to hygiene and infection control protocols;
  - Failure to provide adequate food for residents;
  - Inappropriate withholding of pain medication; and
  - Use of physical or chemical restraints to restrain or sedate residents.
- May be enforced with FCA actions for upcoding.
- Although developed prior to COVID-19, the Initiative has already included investigations into nursing homes and SNFs for allegedly inadequate COVID-19 response.

COVID-19 Legislative and Regulatory Changes

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COVID-19 Developments

January 31, 2020: HHS Secretary Alex Azar declares a public health emergency (PHE) for the entire United States.

March 13, 2020: President Trump declares a national emergency (retroactive effective date: March 1).

March 17, 2020: CMS expands Medicare coverage of telehealth (retroactive effective date: March 6).

March 13, 2020: Pursuant to the national emergency order, CMS issues Section 1135 blanket waivers for healthcare providers (retroactive effective date: March 1).

March 30, 2020: CMS issues additional Section 1135 blanket waivers to give providers additional flexibility to respond to the COVID-19 pandemic (retroactive effective date: March 1).

March 30, 2020: CMS issues 18 nation-wide Stark waivers that exempt healthcare entities from Stark Law sanctions, provided they meet certain conditions (retroactive effective date: March 1).

April 3, 2020: HHS OIG issues a Policy Statement stating that the OIG would not impose administrative sanctions under the Anti-Kickback Statute (AKS) for remuneration covered by most of the Stark Law waivers.

April 23, 2020: H.R. 266 Paycheck Protection Program and Health Care Enhancement Act (Phase 3.5 of Congressional response) passed by Senate into law. Includes $6 million for HHS IG oversight activities.

May 5, 2020: DOJ announces first CARES Act fraud charges.

May 26, 2020: HHS releases OIG Strategic Plan for Oversight of COVID-19 Response and Recovery.

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Telehealth Expansion

CARES Act Provisions

- § 1135 - Waiver of telehealth "originating site" restrictions – At home, anywhere in the country.
- § 3703 – Secretary can waive three-year established patient requirement.
- § 3704 – Permits FQHCs and RHCs to be "distant sites" during a PHE.
- § 3212 – Expands telehealth grants.
- § 3701 – Preferential tax treatment for high-deductible plans that offer telehealth with no co-pays.

Telehealth Waivers

- CMS now allows for more than 80 services to be furnished via telehealth, including Emergency Department visits, initial nursing facility visits and discharge visits, home health, and therapy visits.
- Generally, services may be provided to new patients, not just established patients.
- More flexible remote monitoring (e.g., pulse/oxygen).
- Physicians can supervise clinical staff via virtual technologies when appropriate.

Stark Law Waivers

COVID-Related Purposes

Diagnosis or medically necessary treatment of COVID-19 for any patient or individual
Securing the services of physicians and other practitioners and professionals to furnish medically necessary patient care services, including services not related to the diagnosis and treatment of COVID-19, in response to the outbreak
Ensuring the ability, and/or expanding the capacity, of providers to address patient and community needs due to the outbreak
Expanding the capacity of providers to address patient and community needs due to the outbreak
Shifting the diagnosis and care of patients to appropriate alternative settings due to the outbreak
Addressing medical practice or business interruption due to the outbreak to maintain the availability of medical care and related services to patients and the community

Provider-Specific Waivers and Regulatory Changes: **Home Health Agencies**

- **Aide Supervision**: CMS is waiving the requirement that an RN or other skilled therapy professional make an annual onsite supervisory visit of each aide, but all postponed assessments must be completed **no later than 60 days** after the PHE.
- **QAPI**: CMS is narrowing the required scope of the Quality Assurance and Performance Improvement (QAPI) program to concentrate on infection control issues and adverse events.
- **Patient Assessments**: Occupational therapists, physical therapists and speech language pathologists are allowed to perform initial and comprehensive assessments for all patients receiving therapy services as part of the plan of care, not just for therapy-only patients.
- **Certification and Re-Certification**: NPs, CNSs and PAs are authorized to
  - order, certify and recertify patients for HHA eligibility; and
  - perform the face-to-face encounter for the patients for whom they are certifying eligibility.

Provider-Specific Waivers and Regulatory Changes: **Hospices**

- ✓ **Telehealth**: Hospices are explicitly allowed to use audio-only communications (telephone calls) to provide services to Medicare patients receiving routine home care via telecommunications.
- ✓ **Aide Assessments:** CMS is waiving the requirement that an RN or other skilled therapy professional make an annual onsite supervisory visit of each aide, but all postponed assessments must be completed no later than 60 days after the PHE.
- ✓ **Aide Supervision:** CMS is waiving the requirement for hospices that a nurse conduct an on-site visit every two weeks.
- ✓ **Training:** CMS is postponing the deadline for annual assessments and training.
- ✓ **QAPI:** CMS is narrowing the required scope of the Quality Assurance and Performance Improvement (QAPI) Program to concentrate on infection control issues and adverse events.

Provider-Specific Waivers and Regulatory Changes: **Long-Term Care Facilities (LTCFs)**

LTCFs are required to report:

- weekly to the CDC suspected and confirmed COVID-19 cases among residents and staff, staffing shortages, ventilator capacity and supplies, PPE and hand hygiene supplies, among other information, in an electronic format that CMS will make public; and
- to residents, their representatives, and families by 5:00 pm the next calendar day either a single confirmed COVID-19 infection or three or more residents or staff with new onset of respiratory symptoms occurring within 72 hours of each other.

Provider-Specific Waivers and Regulatory Changes: **LTCFs**

- ✓ **QAPI:** CMS is narrowing the required scope of the Quality Assurance and Performance Improvement (QAPI) program to concentrate on infection control issues and adverse events.
- ✓ **Record Requests:** CMS is extending the response time to provide records to residents, when requested, from two to ten working days.
- ✓ **Nurse Aide Training:** CMS is postponing deadline for nurse aide 12-hour training requirement **until after the PHE ends.**
- ✓ **Discharge Planning:** CMS is waiving the discharge planning requirement that LTCFs assist residents and their representatives in selecting a post-acute care provider using data, such as standardized patient assessment data, quality measures and resource use.
- ✓ **Paid Feeding Assistants**: Announced on May 11, CMS has lowered the minimum hours training requirement for paid feeding assistants from eight hours to one hour but does not modify the training content, which includes infection control and other required elements.
- ✓ **Life Safety Code Requirements**: Announced on May 11, CMS is waiving prescriptive requirements for the placement of alcohol-based hand rub dispensers. In lieu of fire drills, CMS is permitting a documented orientation program related to the current fire plan. CMS is waiving temporary construction requirements that would otherwise not permit temporary walls and barriers between patients.

Provider-Specific Waivers and Regulatory Changes: **Ambulatory Surgery Centers (ASCs)**

- ✓CMS is waiving the medical staffing requirement that medical staff privileges must be periodically reappraised.
- ✓CMS believes that loosening this requirement will allow physicians whose privileges will expire to continue practicing at the ASC without the need for reappraisal.

Provider-Specific Waivers and Regulatory Changes: **Inpatient Rehabilitation Facilities**

- ✓ The CARES Act requires the Secretary to waive the "3 hour rule," which requires generally 15 hours/week of therapy.
  - CMS implements this requirement during the PHE for beneficiaries in a hospital-based or freestanding IRF.
  - Applies regardless of whether patient was admitted for IRF care or to relieve acute care hospital capacity, but CMS states that IRFs should strive to still provide typical IRF.
- ✓ CMS is allowing freestanding IRFs to admit acute care patients that do not meet the IRF coverage requirements to provide acute care hospitals with surge capacity.
  - The flexibility is available for freestanding IRF hospitals when the state is in Phase 1 or prior to entering Phase 1, consistent with the Guidelines for Opening Up America, but not when the state is in Phase 2 or 3.

Enforcement Areas of Focus

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Enforcement Priorities

- ✓ Physician arrangements
- ✓ Opioid crisis
- ✓ 60-Day Medicare Overpayment Rule
- ✓ Telehealth fraud
- ✓ "Meaningful Use" of electronic health records (EHR)
- ✓ Medically unnecessary services
- ✓ HIPAA enforcement

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Physician Arrangements

AKS and Stark violations continue to be an area of focus for government enforcement.

- AKS is a criminal statute but can also result in civil enforcement.
- The Stark Law is a strict liability statute – not intent-based.
- AKS and Stark issues implicate significant potential damages and penalties and thus continue to attract the attention of whistleblowers and regulators.
- CMS and OIG proposed changes to the Stark Law and AKS in October 2019, but enforcement in this area is likely to continue.

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Use of the FCA to Combat Opioid Crisis

The opioid crisis continues to be a significant enforcement focus.

- In 2018, DOJ created the Prescription Interdiction & Litigation (PIL) Task Force to focus and coordinate its efforts to combat the opioid crisis.
- In 2019, the government continued bringing enforcement actions to combat the crisis.

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60-Day Medicare Overpayment Rule

- Compliance with the 60-Day Medicare Overpayment Rule (which requires the reporting and returning of overpayments) is particularly complex given that issues can arise in numerous different contexts.
- Obligations with respect to the 60-Day Overpayment Rule are critical to evaluating:
  - response to external audits;
  - response to issues identified through internal investigations and audits; and
  - potential self-disclosure obligations.
- Low-hanging fruit for whistleblowers.
- Facts and circumstances analysis opens the door to second-guessing of a provider's diligence.

Telehealth

Telehealth Medicare claims have dramatically increased.

- The Health Resources and Services Administration (HRSA) of HHS defines telehealth as "the use of electronic information and telecommunications technologies to support and promote long-distance clinical healthcare, patient and professional health-related education, public health and health administration."
- Telehealth services are Part B services under Medicare.
- A 2018 HHS OIG report found that Medicare telehealth spending increased from **$61,302** in 2001 to **$17,601,996** in 2015.
  - The same report showed that, in a sample of 100 Medicare telehealth claims, 31 were unallowable.

Telehealth

Potential compliance issues can include:

- failure to meet billing requirements;
- licensure issues;
- controlled substances prescribing issues;
- privacy and security issues; and
- anti-markup issues.

Telehealth

- **Operation Brace Yourself**: In April 2019, DOJ announced charges against 24 individuals in a telemedicine fraud scheme that resulted in over **$1.2 billion** in losses.
- **Operation Double Helix (Sept. 2019)** – Involved fraudulent billing for genetic testing which resulted in over **$2.1 billion** in losses to Medicare.
- Prosecutions under Operations Brace Yourself and Double Helix have continued into 2020.
- While telehealth regulation has become more flexible in response to the pandemic, expect enforcement focus to continue.

"Meaningful Use" of EHR

CMS has an EHR Meaningful Use incentive program (now called the "Promoting Interoperability Program")

- To obtain funding, providers must make "meaningful use" of the EHR technology.
- The concept of "meaningful use" is aligned with five policy priorities set by HHS:
  - —Improve quality, safety, efficiency, and reduce health disparities;
  - —Engage patients and families in their health;
  - —Improve care coordination;
  - —Improve population and public health; and
  - —Maintain privacy and security of patient health information.

"Meaningful Use" of EHR

Recent FCA settlements have centered on false claims for EHR incentive payments.

- As in years past, DOJ has brought FCA enforcement actions for submitting false claims pursuant to the EHR Incentive Program (or causing false claims to be submitted to the Program).
  - In February 2019, Greenway Health, a developer of EHR software, agreed to pay $57.25 million to resolve claims that it misrepresented the capabilities of its software and, in selling and promoting that software, caused false claims to be submitted for EHR incentive payments.

"Electronic Health Records can be key to an integrated health system providing improved care. Putting patients at risk will result in intensive investigation and compliance obligations."
– Derrick Jackson, Special Agent in Charge, HHS OIG, in DOJ Press Release announcing Greenway Health settlement

"Meaningful Use" of EHR

After settling allegations of EHR-related FCA violations, companies also have entered into Corporate Integrity Agreements (CIAs) with the government.

- A CIA typically lasts five years and may, among other possibilities, require the company to:
  - "hire a compliance officer/appoint a compliance committee"
  - "develop written standards and policies"
  - "implement a comprehensive employee training program"
  - "report overpayments, reportable events, and ongoing investigations/legal proceedings"
  - "provide an implementation report and annual reports to OIG on the status of the entity's compliance activities"
- As part of its settlement with DOJ, Greenway entered into a five-year CIA with HHS-OIG covering the company's EHR software. Greenway must retain an Independent Review Organization to assess Greenway's software quality control and compliance systems and to review Greenway's arrangements with healthcare providers to ensure compliance with the Anti-Kickback Statute.

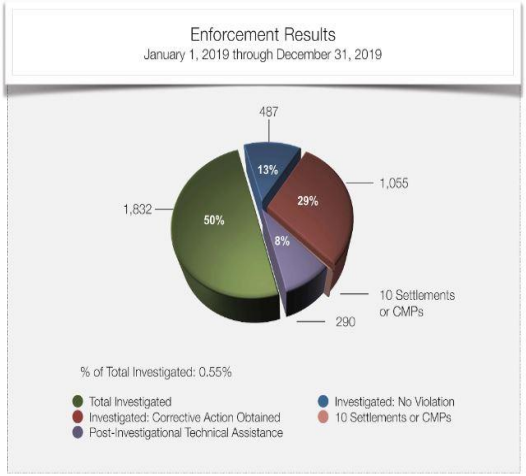
Medically Unnecessary Services

Billing for medically unnecessary services remains a focus of FCA enforcement.

- "Medically necessary" services and supplies are those "needed to diagnose or treat an illness, injury, condition, disease or its symptoms and that meet accepted standards of medicine."
- Violation mentioned most often in FCA settlements (2017-2018) was billing for medically unnecessary services.
  - The next most-mentioned violation appeared about half as often.

HIPAA Enforcement

- Overall the privacy and security landscape continues to grow more complex.
- HHS Office of Civil Rights (OCR)—the agency that enforces the HIPAA Privacy, Security, and Breach Notification Rules—has continued to expand its enforcement activity.
- 2018 represented a record-breaking year in terms of HIPAA enforcement activity.
- The total number of HIPAA cases increased in 2019.



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HIPAA Enforcement

- Areas of recent HIPAA enforcement activity include:
  - Data hacking;
  - Compliance with patient rights of access;
    - OCR area of focus and part of OCR's Right of Access initiative
  - Improper use of social media;
  - Unencrypted data;
  - Failure to conduct comprehensive risk analysis; and
  - IT challenges.

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Post-Pandemic Predictions

- Although there will be some reversion back to pre-pandemic requirements, we anticipate some regulatory shifts will remain in place.
  - Example: We expect telehealth expansion to continue as patients, providers, and payors become more comfortable with its use.

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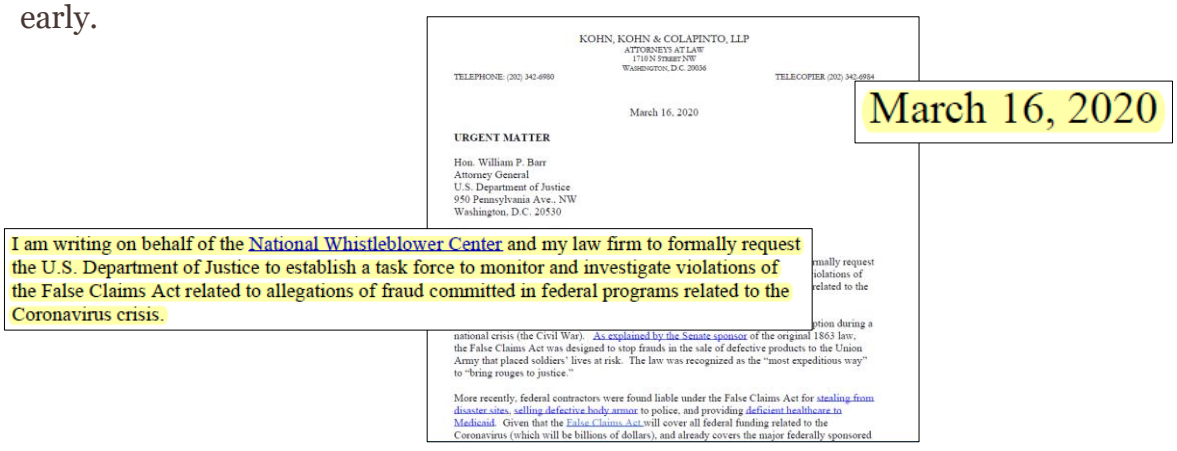
Post-Pandemic Predictions

- Whistleblower community began calling for False Claims Act enforcement very early.



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March 16, 2020

URGENT MATTER

Hon. William P. Barr
Attorney General
U.S. Department of Justice
950 Pennsylvania Ave., NW
Washington, D.C. 20530

I am writing on behalf of the National Whistleblower Center and my law firm to formally request the U.S. Department of Justice to establish a task force to monitor and investigate violations of the False Claims Act related to allegations of fraud committed in federal programs related to the Coronavirus crisis.

March 16, 2020

national crisis (the Civil War). As explained by the Senate sponsor of the original 1863 law, the False Claims Act was designed to stop frauds in the sale of defective products to the Union Army that placed soldiers' lives at risk. The law was recognized as the "most expeditious way" to "bring rouges to justice."

More recently, federal contractors were found liable under the False Claims Act for stealing from disaster sites, selling defective body armor to police, and providing deficient healthcare to Medicaid. Given that the False Claims Act will cover all federal funding related to the Coronavirus (which will be billions of dollars), and already covers the major federally sponsored

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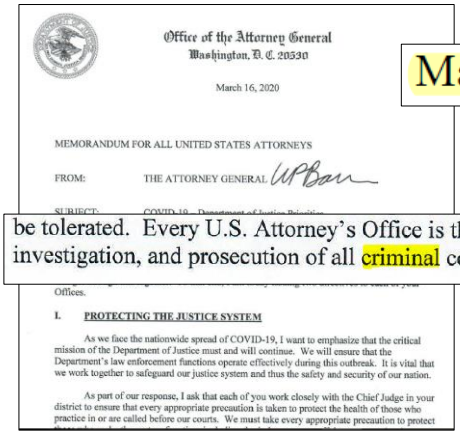
Post-Pandemic Predictions

- The DOJ has also emphasized that COVID-19-related enforcement is a top priority.



Office of the Attorney General
Washington, D. C. 20530

March 16, 2020

March 16, 2020

MEMORANDUM FOR ALL UNITED STATES ATTORNEYS

FROM: THE ATTORNEY GENERAL

be tolerated. Every U.S. Attorney's Office is thus hereby directed to prioritize the detection, investigation, and prosecution of all criminal conduct related to the current pandemic.

Offices.

I. PROTECTING THE JUSTICE SYSTEM

As we face the nationwide spread of COVID-19, I want to emphasize that the critical mission of the Department of Justice must and will continue. We will ensure that the Department's law enforcement functions operate effectively during this outbreak. It is vital that we work together to safeguard our justice system and thus the safety and security of our nation.

As part of our response, I ask that each of you work closely with the Chief Judge in your district to ensure that every appropriate precaution is taken to protect the health of those who practice in or are called before our courts. We must take every appropriate precaution to protect

Post-Pandemic Predictions

- Anticipated enforcement priorities following the pandemic include:
  - Medical necessity;
  - Telemedicine billing;
  - Potential upcoding; and
  - Improper use of Coronavirus Aid, Relief, and Economic Security (CARES) Act provider relief funds.

Key Takeaways and Compliance Strategies

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Key Takeaways

- Enforcement will broaden to include pandemic-related issues. However, existing, pre-pandemic enforcement areas of focus will remain high priority.
- FCA cases are becoming more litigious, and healthcare entities should react accordingly.
- Effective Compliance Programs continue to increase in importance.
- Fraud enforcement topics follow public policy focus and the evolution of technology.

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COVID-19 Compliance Strategies

Organizational risk profile → risk profile in June 2020 is different from risk profile in 2019

- Focus on how a Compliance Program reacts to new risk areas and pivots to address new risks.
- Benefits of reassessing 2020 auditing and monitoring plans.
- Coordination between Legal and Compliance is important.
  - Interpretation of COVID-19 authority and guidance.
- Consider strategies for reverting back to pre-pandemic regulatory compliance after emergency period.

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Questions

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