

ReedSmith

Navigating the New Normal: Remote Compliance and Virtual Investigations

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Driving progress
through partnership

Disclaimer

This presentation is not intended to provide legal advice to be used in a specific fact situation

The contents are for information purposes only

Welcome and Agenda

- Key risk areas for internal investigations
- Access and confidentiality for employees to raise concerns in remote environments
- Response to concerns that are raised:
 - Investigating those concerns
 - Conducting telephone and Zoom interviews
 - Completing the investigation in a timely manner
 - Ensuring that remedial measures are put in place



Key Risk Areas for Internal Investigations

Risk Areas Include . . .

- Areas highlighted in OIG Work Plan
- Potential non-compliance with Stark Law or Anti-Kickback Statute, including excessive physician compensation
 - Availability of waivers in COVID era may be challenged
- Representations to the government to obtain federal funds
- Compliance with CARES Act terms and conditions
- Audit risk, and risk of allegations brought under the False Claims Act, especially by whistleblowers



OIG & False Claims Act Scrutiny

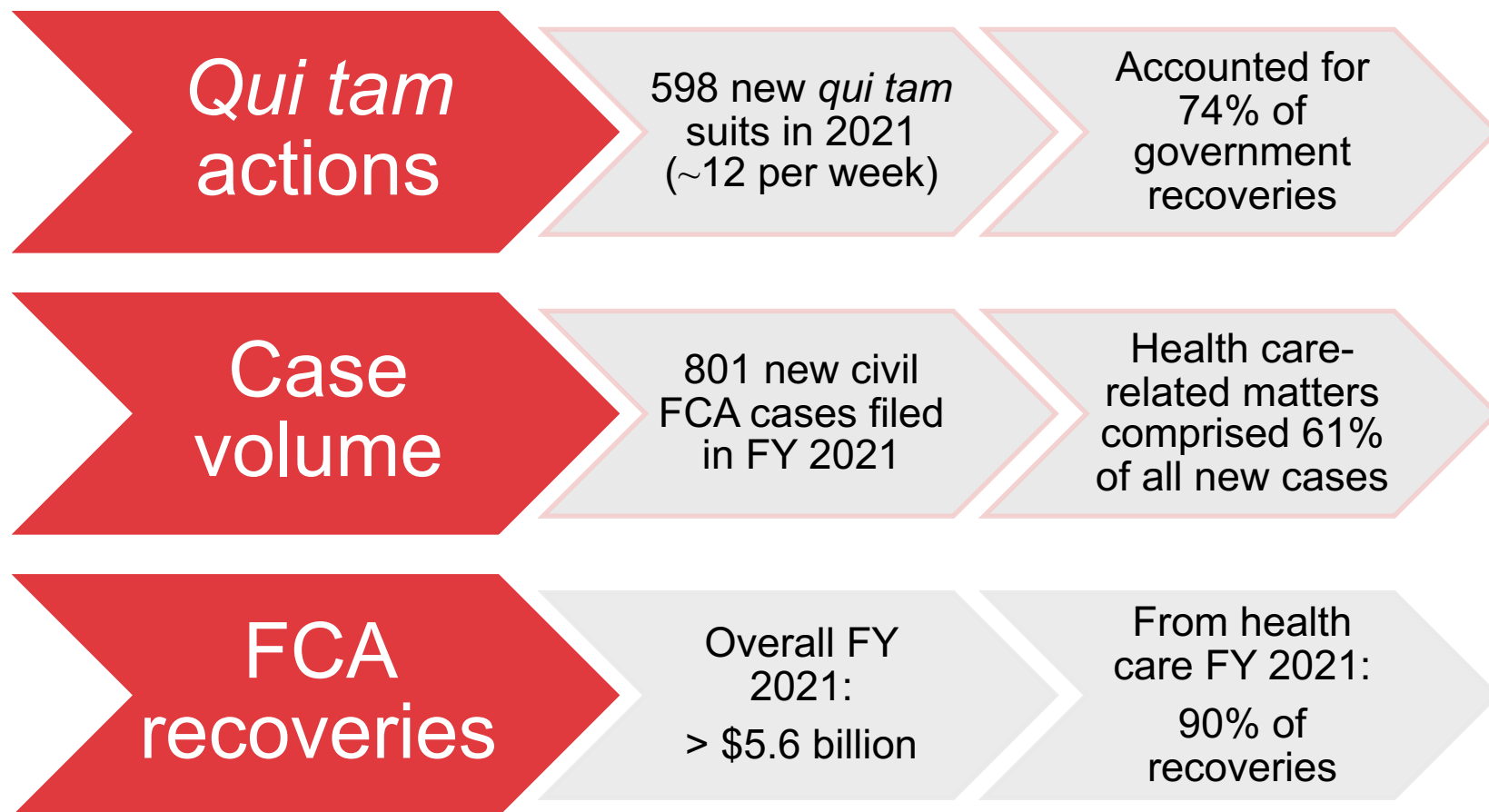
Key Risk Areas for Internal Investigations

OIG Work Plan & Recent Additions

- Tells you what OIG will be auditing and, thus, what you should be looking at, including for internal investigations
- Regularly updated at: <https://oig.hhs.gov/reports-and-publications/workplan/updates.asp>
- Active items listed at: <https://oig.hhs.gov/reports-and-publications/workplan/active-item-table.asp>
- Recent items include:
 - COVID-19 Vaccination Status of Nursing Home Staff
 - Use of Medications for Opioid Use Disorder (MOUD) in Medicaid
 - Nursing Home Capabilities and Collaboration to Ensure Resident Care During Emergencies

False Claims Act Enforcement

“Busy practice area” is an understatement



FCA Risk Areas Include . . .

- Areas highlighted in OIG Work Plan
- Potential non-compliance with Stark Law or Anti-Kickback Statute, including excessive physician compensation
 - DOJ received a \$140M default judgment for allegations of improper physician compensation, among other things, against SC clinics and labs (Sept. 2021)
 - Availability of waivers in COVID era may be challenged
- Representations to the government to obtain federal funds
 - PA Medicare Advantage plan pays \$2.25M to resolve allegations of inflated plan bids (Sept. 2020)

FCA Risk Areas Include . . .

- On February 23, 2022, Chief Counsel to the Inspector General (DHHS, OIG), Gregory E. Demske, Delivered Remarks at the Federal Bar Association Qui Tam Conference and listed the following as some of OIG's priorities:
 - Pandemic-Related Fraud (CARES Act Relief Funds)
 - Medicare Advantage (Part C)
 - The Opioid Epidemic
 - Telehealth
 - Nursing Homes

How an FCA Case Works

Steps:

1. Relator files the case under seal
2. Government investigates
3. Government decides if it will prosecute the case
4. Relator may continue to prosecute even if government declines
5. Complaint is unsealed and litigation begins

Active litigation of declined *qui tam* cases by sophisticated private law firms is one of the most significant enforcement trends in the last several years



Damages for an FCA Violation

- A civil penalty **for each false claim** of up to over \$22,000
- Plus up to **three times** the amount of damages
- Reasonable costs, expenses and attorneys' fees that relators pay or incur in successfully prosecuting *qui tam* actions
- May lead to **exclusion** from participation in government programs (e.g., Medicare)
- Enormous financial pressure to resolve these cases



The CARES Act

Key Risk Areas for Internal Investigations

The CARES Act

Coronavirus Aid, Relief, & Economic Security (CARES)

- \$100 billion relief to support health care-related expenses or lost revenue due to COVID-19 and testing/treatment
- Both general and targeted allocations (high impact areas, treatment of uninsured, etc.)
- These are **payments**, not **loans** with forgiveness criteria, but retaining the payments requires compliance with Terms & Conditions
- **T&C warning**: Any deliberate omission, misrepresentation, or falsification of information in application or future reports can result in criminal civil, or administrative penalties
 - T&C state that a provider's "commitment to full compliance with all Terms and Conditions is material to the Secretary's decision to disburse these funds to you"
 - Government's attempt to shore up "materiality" argument for future FCA litigation; uncertain success

CARES Act: Terms & Conditions



DEPARTMENT OF HEALTH & HUMAN SERVICES

Acceptance of Terms and Conditions

If you receive a payment from funds appropriated in the Public Health and Social Services Emergency Fund for provider relief (“Relief Fund”) under Public Law 116-136 and retain that payment for at least 90 days without contacting HHS regarding remittance of those funds, you are deemed to have accepted the following Terms and Conditions. Please also indicate your acceptance below. This is not an exhaustive list and you must comply with any other relevant statutes and regulations, as applicable.

Your commitment to full compliance with all Terms and Conditions is material to the Secretary’s decision to disburse these funds to you. Non-compliance with any Term or Condition is grounds for the Secretary to recoup some or all of the payment made from the Relief Fund.

CARES Act

Example Terms & Conditions

- Cannot be used to reimburse expenses/losses that have been reimbursed from other sources, or which other sources are obligated to reimburse
 - **E.g.** Insurance policy subsequently reimburses expenses, must repay funds from HHS
- Funds cannot be used for certain purposes
 - **E.g.** Excessive executive pay, gun control advocacy, abortion, lobbying, embryo research, promotion of legalization of controlled substances, pornography, human trafficking, and more

CARES Act

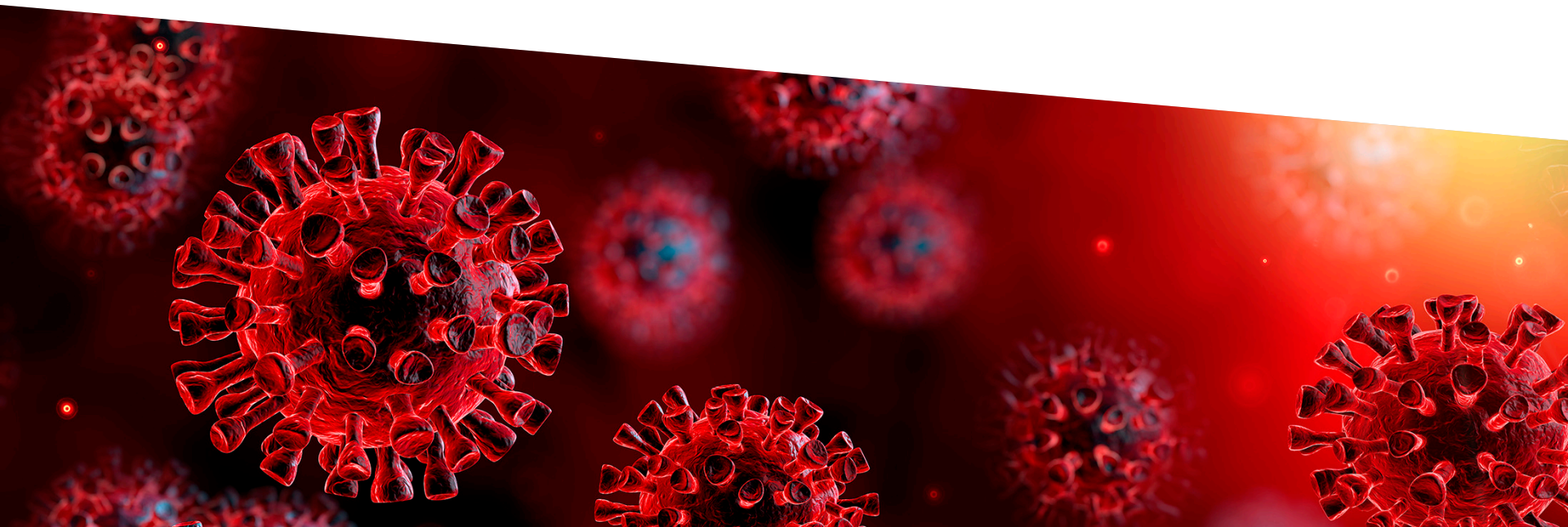
Enforcement

- Special Inspector General for Pandemic Recovery (SIGPR)
 - Modeled after SIGTARP following 2008 financial collapse
 - SIGTARP investigations resulted in 380 convictions (97 percent conviction rate) and recovery of > \$11 billion
- Attorney General Merrick Garland announced the COVID-19 Fraud Enforcement Task Force on May 17, 2021
 - “The Department of Justice will use every available federal tool – including criminal, civil, and administrative actions – to combat and prevent COVID-19 related fraud. We look forward to working with our federal government colleagues to bring to justice those who seek to profit unlawfully from the pandemic.”
 - Task Force includes DOJ Criminal and Civil Divisions, Executive Office for the U.S. Attorneys, FBI, the Departments of Labor, Treasury, and Homeland Security, SIGPR, SBA, and Pandemic Response Accountability Committee

CARES Act

Enforcement

- **March 2022 – First “Cyber-Fraud” Settlement Was with Healthcare Provider:** Settled with the DOJ for almost a million dollars for allegedly lax data protection practices for their EMR system
- **April 2022 – A Physician Group:** Settled with the DOJ to pay \$24.6 million for unnecessary testing and telehealth visits, improper remuneration to physicians, and making a false statement in connection with receiving PPP funds
- **April 2022 – Nationwide coordinated action:** DOJ charged 21 individuals, including physicians and healthcare executives, in connection with almost \$150 million in false claims related to CARES Act funds and other COVID-19 related claims
- **On OIG’s Active Item Table – Audit of CARES Act Provider Relief Funds – Payments to Health Care Providers That Applied for General Distribution Under Phases 1, 2, and 3**



Other COVID Compliance Risks

Potential Risk Areas for Internal Investigations

COVID-19 Vaccine-related Enforcement

- Distributing fake CDC COVID-19 vaccination cards
 - Several doctors in Texas and California charged with distributing fake vaccine cards
 - Used their access to identify real COVID-19 vaccine lot numbers to falsify vaccine records
 - Using blank COVID-19 vaccination record card to forge hundreds of fake vaccine cards
- Distributing fake cures
 - Calling them “homeoprophylaxis immunizations”
 - Providing fake vaccine cards related to those “immunizations”

Vaccine Testing

- Providing false negative COVID-19 tests at the airport so travelers could fly
- Billing for office visits that never took place related to COVID-19 tests that were performed at the clinic's mobile testing sites
- Upcoding COVID-19 testing patient visits to “moderate-complexity office visits” when they took five minutes or less



Remote Investigations: COVID and Beyond



Access and confidentiality for employees to raise concerns with compliance officer and team

The Biggest Risk of All

Motivated whistleblowers

- Strategies for mitigating whistleblower risk
 - Now is the time for an active compliance program
 - Listen to your employees' concerns
 - Exit interview strategies (especially for laid off or furloughed employees)



Response to concerns:

- Investigating those concerns
- Conducting telephone and Zoom interviews
- Completing the investigation in a timely manner
- Ensuring that remedial measures are put in place

Taking Your Investigations Online

Virtual witness interviews

Pros

- Need for speed
- No travel necessary
- Quickly address employee concerns
- Faster self-reporting and response

Cons

- Employee anxiety
- Harder to build rapport, read the person
- Difficulty sharing documents
- Employees might take screenshots of shared documents

Step 1: Considering the risks & rewards



Information
compromise

Risk. Employees might take screen shots of shared documents.



Employee
anxiety

Risk. Virtual barrier to reassurance and empathy with a distressed employee.



Observation

Risk. Difficulties sharing documents and managing technology.



Feed the
need for speed

Reward. Virtual interviews allow quick access to employees without travel.



Employee
assurance.

Reward. Quickly address employee concerns.



Rapid regulator
response

Reward. Faster self-reporting and response to requests.

Taking Your Investigations Online

Virtual witness interviews

- Ensure that the parties involved and being interviewed feel comfortable
- Breakout rooms to consult with representative or attorney
- Private messaging and recording functionality
- Encryption, secure link, local data regulations
- Ground rules, manage expectations
- Do a test call
- Anticipate technical issues

Step 2: Selecting your tech



Breakout rooms

Can be useful if an interviewee needs to liaise with a representative or attorney.



Chat functions

Consider whether to allow private messaging during the meeting.



Recording

Will you record, if so where will you save – cloud/local?



Employee capabilities

Can the interviewee use the platform. Do they have bandwidth limitations.



Documents

Functionality for sharing and highlighting documents.

Step 3: Ensuring security



Encryption

Check your platform has end to end encryption throughout the meeting.



Access

Use a secure link, password protect and admit from waiting room.



Interview room integrity

Set ground rules. Ensure the witness is alone unless authorised.



Data protection compliance

Check document share will comply with local data regulations.

Step 4: Planning & testing



Employee representatives

Does the interviewee need a representative/attorney assistance.



Legal attendees

Consider additional lawyers to assist observation and legal compliance.



Ground rules

Set in advance with interviewee/manage expectations.



Legal

Ensure compliance with local employment law/contractual rights.



Technical assistance

Identify who will resolve technical issues.



Test call

It's a no brainer.

Step 5: What to do on the day



Smart questioning

Anticipate response time lags, observe micro expressions.



Keep it brief

Video interviews can be more tiring for all concerned.



Avoid information overload

Concentrate on key documents, highlighted in advance.



Technical issues

Keep calm, troubleshoot, engage technical assistance if required.

Turning Information into Insights

- Using business analytics to uncover and quantify new risks created by decisions made during COVID
- Perform an internal discovery and diagnosis exercise
- Test whether your expectations and assumptions match actual business processes and behavior
- Deliver valuable solutions to your business partners
- This doesn't have to end when COVID ends!

What's Likely Here to Stay?

- Incorporating technology and remote practices for the long term
- Adapting to work-from-home when conducting internal investigations
- Ensuring flexibility in responding to both external and internal concerns

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