

# WHEN THE FEDS COME KNOCKIN'

WHAT TO DO WHEN THE GOVERNMENT DECIDES TO INVESTIGATE  
STATE BAR OF MICHIGAN HEALTH CARE LAW SECTION — SEPTEMBER 19, 2023

FLANNERY  

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# INTRO TO HEALTH CARE FRAUD CASES

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- RECENT STATISTICS
- MICHIGAN'S RESPONSE
- WHY DOES IT MATTER?
- INVESTIGATION ORIGINS

# HEALTH CARE FRAUD INVESTIGATIONS: GOING STRONG

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## FY 2022 Statistics

- \$2.73 billion in expected federal investigative recoveries
- 710 new criminal healthcare fraud investigations opened
- 736 new civil healthcare fraud investigations
- 2,332 exclusions from federal healthcare programs

**Source:** U.S. Dept. of Health and Human Services Office of Inspector General, *Semi-Annual Report to Congress* (Apr. 1, 2022 – Sept. 30, 2022), <https://www.oig.hhs.gov/reports-and-publications/archives/semiannual/2022/fall-sar-2022.pdf>

# HEALTH CARE FRAUD INVESTIGATIONS: GOING STRONG

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## Michigan Perspective

- DOJ Health Care Fraud Strike Force
  - Interagency team of investigators and prosecutors
  - Detroit is one of only 14 cities with a HCF Strike Force
- U.S. Attorney's Offices
  - Dedicated Health Care Fraud Section in Detroit
- State of Michigan
  - Attorney General's Office – Health Care Fraud Division
- Nationwide takedowns

# WHY IMPORTANT?

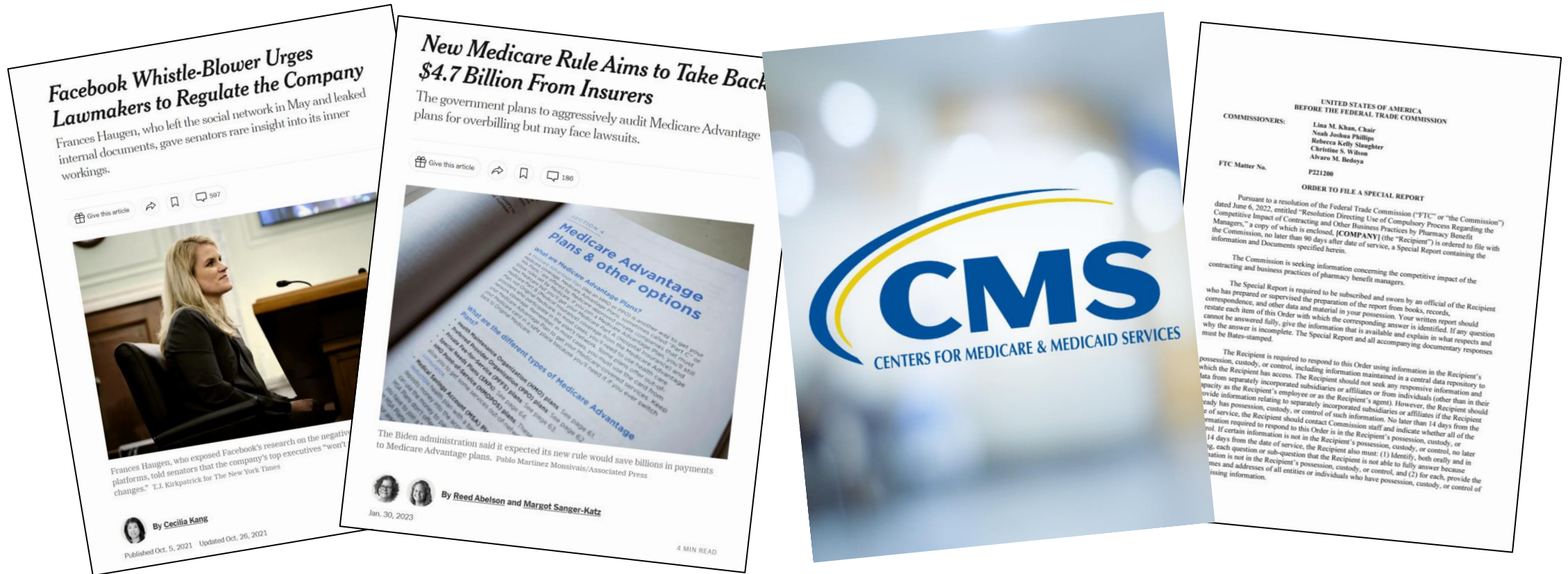
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- Business Disruption
- Lost Productivity
- Personal Toll
- Reputational Harm
- Professional Fees
- Length of Investigation
- Settlement



Source: Hillshire Farm, Unsplash.com

# HOW INVESTIGATIONS START



Sources: New York Times; FTC.gov

# WHAT THE FEDS DO BEFORE THEY COME KNOCKING

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- Witness interviews
- Data Review
- Subpoena to third parties
- Surveillance
- Email search warrants
- Undercover work
- Wiretaps



# WRITTEN REQUESTS FOR INFORMATION

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- GRAND JURY
- ADMINISTRATIVE SUBPOENAS
- CIVIL INVESTIGATIVE DEMANDS
- ... AND MORE

# OVERVIEW

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- **Knowns:**

- Takeaways from information requests themselves
- Anything you can learn from discussions with government

- **Unknowns:**

- Status of client

- **Significant Risks:**

- Potential for alleged obstruction
- Potential subject matter waiver

- **Necessary Considerations:**

- Privilege review
- Option to assert act of production privilege
- Responsiveness/scope limitations
- Internal investigation/interviews for context
- Reduce business disruption
- Maintain **government** and **client** trust

# GRAND JURY SUBPOENAS

- Confirms grand jury investigation of potential *criminal* conduct
- Subpoena *duces tecum* vs. testimonial subpoena
- Almost never found to be irrelevant or beyond grand jury's authority
- Failure to comply can have serious penalties, such as monetary fines, or even imprisonment

AO 110 (Rev. 06/06) Subpoena to Testify Before a Grand Jury

UNITED STATES DISTRICT COURT  
for the  
District of Columbia ☒

SUBPOENA TO TESTIFY BEFORE A GRAND JURY

To: Acme Corp., 1225 Parker Road, Arlington, Virginia

**YOU ARE COMMANDED** to appear in this United States district court at the time, date, and place shown below to testify before the court's grand jury. When you arrive, you must remain at the court until the judge or a court officer allows you to leave.

Place: United States Courthouse Washington DC	Date and Time: 10/07/2020 11:25 am
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You must also bring with you the following documents, electronically stored information, or objects (blank if not applicable):

In lieu of personal appearance, you may provide the following documents to Assistant United States Attorney Jane Smith at the address below.

All documents related to Department of Defense contract no. 1234567.  
All communications related to Department of Defense contract no. 1234567.

Date: 10/07/2020 CLERK OF COURT

\_\_\_\_\_  
Signature of Clerk or Deputy Clerk

The name, address, e-mail, and telephone number of the United States attorney, or assistant United States attorney, who requests this subpoena, are:

Jane Smith  
US Attorney's Office for the District of Columbia  
555 Fourth Street, NW  
Washington DC 20530

# ADMINISTRATIVE SUBPOENAS & CIVIL INVESTIGATIVE DEMANDS (CIDs)

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## Administrative Subpoenas:

- Presume responses will be shared with criminal division
- Not necessarily indicative that criminal/civil fraud investigation has been opened
- Validity is determined by applicable statute
- Scope/jurisdiction may differ according to statutory authority

## CIDs:

- Provide civil investigatory power for DOJ officials *before* commencement of civil proceeding
- Scope can be very broad. May compel production of documents, written interrogatory responses, or oral testimony
- Increasingly common in healthcare FCA cases

# OTHER TYPES OF INFORMATION REQUESTS

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- Private payor inquiry or audit
- Medicare/Medicaid audits
- Other regulatory requests
- Requests in parallel or related proceedings
- “Knock and Talk” interview requests

# “KNOCK AND TALK” INTERVIEWS

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## Ways to Prepare Clients in Advance:

- Clients May:
  - Advise employees of the criminal risks of responding and of their right to consult counsel before agreeing to be interviewed
  - Ask employees to advise them when contacted with an interview request
  - Offer to provide counsel to employees
- Clients MAY NOT:
  - Tell staff not to respond or threaten adverse employment consequences
  - “Obstruction” is a crime / other antagonistic behavior is bad for business

# SEARCH WARRANTS AND OTHER SEIZURES OF EVIDENCE

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- SEARCH WARRANT
- ADMINISTRATIVE INSPECTION WARRANTS (AIW)
- STATE LEVEL/BOARD LAWYER DOCUMENT DEMANDS

# SEARCH WARRANTS

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- Court order that authorizes government to conduct a search for evidence of a crime and to confiscate evidence they find.
- **Knowns:**
  - Investigation is more developed/Criminal
- **Unknowns:**
  - Scope of records/evidence targeted (unknown at time of search)
- **Goals:**
  - Reduce business disruption
  - Limit legal exposure/risk
  - Obtain information from government
  - Get Control Early



# SEARCH WARRANTS

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- Paper records
  - Patient charts are gone
  - Facilitate copying of records
- Electronic devices
  - Imaging the devices, including phones
- Cloud-based storage platforms

# HOW TO PROCEED IN RESPONSE TO AN INQUIRY

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- INTERNAL INVESTIGATION BEST PRACTICES
- INVESTIGATIVE STEPS
- ISSUES TO KEEP IN MIND

# INTERNAL INVESTIGATION BEST PRACTICES

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- Usually initiated after search warrant executed or concurrent with subpoena response
  - Set timetable – don't delay
  - Be proactive: don't wait for indictment
- Gather facts to assess risks and advise client
- Scope varies depending on size of client and nature of allegations
  - Consider commissioning a billing review
- Develop investigation team structure
- Be aware of whistleblowers or other employee issues
  - Determine whether individual counsel necessary

# INTERNAL INVESTIGATIONS: STEP-BY-STEP

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- Consider co-counsel
- Engage e-discovery vendor
- Conduct document review
- Schedule interviews (current and former employees)
- Hire experts (e.g., forensic accountants, subject matter)
- Develop defense and cooperate with government requests
- Prepare litigation plan if no declination/plea/settlement
- Issue report and recommendations, if appropriate

# ISSUES TO KEEP IN MIND

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## Common Issues in Healthcare Matters

- Upcoding/Other Billing Fraud
- Medical Necessity
- Stark Law/AKS Violations
- Mail/Wire Fraud
- Tax Issues
- False Claims Act Exposure
  - Known overpayment / Reverse False Claim
- Overlap with other Investigations (e.g., Public Corruption, Bankruptcy, SEC, etc.)

# INTERACTIONS WITH GOVERNMENT OFFICIALS

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- CLIENT STATUS
- BEST PRACTICES
- ATTORNEY INTERACTIONS
- CLIENT INTERACTIONS

# CLIENT STATUS

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- Establish and confirm status of client
  - Keep track over time. Always subject to change



# BEST PRACTICES FOR INTERACTING WITH LAW ENFORCEMENT

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- Investigators are trained to get information from client
- Know your investigators and prosecutors
- Practice, Practice, Practice before client interfaces with Government
- Risk avoidance – false statements are criminal



# ATTORNEY INTERACTIONS WITH GOVERNMENT

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- Initial communications with Government set the tone for the investigation/case
- Choice of counsel matters
  - Experience
  - Relationship with prosecutor/agents fosters trust
- Less is more – don't offer information not requested
- Take detailed notes
- Avoid discussing topics not yet covered with client
- Consider attorney proffers in lieu of client interviews

# CLIENT INTERACTIONS WITH GOVERNMENT

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- Proceed with extreme caution
- Lay groundwork before interview
  - Know client status before agreeing to interview
- Request written *Kastigar* letter/proffer agreement confirming scope of interview
- Discuss advantages and disadvantages of conducting proffer with government
- Logistically:
  - May take hours – prepare your client and bring a notetaker
  - Many agents and attorneys may attend – record all attendees

## POSSIBLE PATHS TO RESOLUTION

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- PREPARE FOR ALL POSSIBILITIES
- SEEK DECLINATION
- ANALYZE POTENTIAL GOVERNMENT CONSIDERATIONS IN DETERMINING OUTCOMES
- VOLUNTARY SELF-DISCLOSURE

# PREPARE FOR ALL POSSIBLE OUTCOMES

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- Global resolutions
- Plea offers
- Investigations can stretch for months or years – *with no obligation to tell you your client is off the hook!*

# CONSIDER DECLINATION PRESENTATION...

*...BUT BE OPEN TO OTHER RESOLUTIONS*

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- In appropriate circumstances, it may make sense to detail for the government why criminal declination is important
- Formal declinations are rare, so consider other viable options
- NPA/DPA: negotiated settlements (without pleading guilty or conviction) where company agrees to restitution, forfeiture, monetary sanctions, and other reforms
  - **NPA**s – no charges, but agreement reached between parties
  - **DPA**s – formal charges/agree to dismiss, monitors, cooperation, admit wrongful conduct
- Corporate Integrity Agreement (CIA) / Independent Compliance Monitor

# RESOLUTION CONSIDERATIONS FOR GOVERNMENT

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## CONSIDERATIONS FOR CHARGING CORPORATIONS:

- Nature of offense (risk of harm to public)
- Pervasiveness (management)
- History of wrongdoing or compliance
- Cooperation and disclosure
- Remedial Actions/Compliance Program
- Available civil remedies
- Prosecution of individuals

### Justice Department seeks to entice companies to be better corporate citizens.

The agency is trying to motivate more people to come forward, through the promise of leniency or other benefits, to identify wrongdoing.

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Lisa Monaco, the deputy attorney general, said that securing more voluntary disclosures would ultimately improve the department's record in corporate criminal enforcement. Anna Moneymaker for The New York Times

By Ephrat Livni  
Sept. 15, 2022

# LESSONS LEARNED



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## RECENT CASE EXAMPLE

# EXAMPLE: ARRAYIT LABORATORIES

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- Allergy testing laboratory
  - 120 allergen panel: food & environmental triggers
  - Micro-array technology = one pass through testing
  - Billed Medicare, Tri-Care & Private Insurers
    - Private Insurers paid up to \$10,000 per test
  - Lack of medical necessity



Image source: Twitter



# EXAMPLE: ARRAYIT LABORATORIES

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- Network of sales representatives national
  - Marketing materials supplied by Arrayit
  - Physicians not educated in billing implications
  - Representatives paid percentage of private insurance revenues
    - Company was careful not to base compensation on Medicare claims
    - Thus a violation of the Eliminating Kickbacks in Recovery Act
  - Company pivots to COVID testing, claiming micro array process can detect C-19 proteins

# EXAMPLE: ARRAYIT LABORATORIES

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- Investigation:
  - COVID fraud data mining
  - Billed vs Paid analysis
    - \$5.9M billed to Medicare, \$63M to private
    - \$290,000 paid by Medicare, \$2M by private
  - Subpoenas to third parties
  - Coordination with FDA and SEC
  - Interviews of physicians, office managers, sales representatives
  - Target interviews: Mark Schena, Renee Schena, Paul Haje and others



Image source: <https://www.atg.wa.gov/robocall-and-telemarketing-scams>

# EXAMPLE: ARRAYIT LABORATORIES

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- Mark Schena Indicted
  - Conspiracy to commit health care fraud (18 U.S.C. § 1349)
  - Health Care Fraud (18 U.S.C § 1347)
  - Conspiracy to Pay Illegal Kickbacks (18 U.S.C. § 371)
  - Payment of Illegal Kickbacks (18 U.S.C. § 220(a))
  - Securities Fraud (15 U.S.C. § 78j & 78 ff)
- Other Defendants all entered into Plea Agreements
  - Paul Haje
  - Two physicians
  - Two sales representatives



Image source: KTUV tv

# EXAMPLE: ARRAYIT LABORATORIES

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- Real and possible collateral damage
  - Sales representatives
  - Ordering physicians who lacked knowledge of:
    - How tests were billed
    - Local Coverage Determinations
  - Investors
  - Patients who relied on test results

# OTHER EXAMPLES: INSYS THERAPEUTICS & ROCHESTER DRUG CO-OPERATIVE

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## **Insys Therapeutics, Inc.**

- Resolution includes:
  - Deferred Prosecution Agreement
  - Corporate Integrity Agreement
  - False Claims Act Settlement
  - \$2 million criminal fine; \$28 million forfeiture
  - Criminal Prosecution of Eight Insys Executives
- Company filed bankruptcy as a result of resolution
- Former CEO sentenced to 66-months' imprisonment

## **Rochester Drug Co-Operative**

- Resolution includes
  - 5-year Deferred Prosecution Agreement with option for 1-year extension at Government's sole discretion
  - Significant compliance measures required
  - \$20 million civil forfeiture
- Criminal charges filed against company's former CEO and Chief Compliance Officer

# CONCLUDING THOUGHTS: COLLABORATIVE SOLUTIONS

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- High stakes
  - Important to engage counsel with appropriate experience and background
  - A poor choice of counsel will make a bad situation worse
- Work collaboratively with gov't investigations experts while adding your substantive experience and knowledge of the client to the case
- Collaborate/stay involved throughout the course of the government's investigation

# Questions?

