

A Practical Response to False Claims Act Investigations

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FCA Cases In The Trump Administration – The Growth Continues

- Healthcare fraud enforcement remains a top priority
- FCA penalties are increasing and the FCA remains a powerful tool in the government's arsenal
- Ongoing DOJ and OIG focus on individual accountability
- Government's continued focus on Corporate Compliance Programs

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Growth Trend Continues

- Health care cases were majority of \$3.7B recovered in FCA in FY17
- DOJ recovered \$425 million from declined cases
- DOJ reported increase in number of FCA recoveries from individuals:
 - Owner of Life Care Centers of America joint and several liability for \$145m settlement
 - Medstar Ambulance
 joint and several liability for \$12.7m settlement
 - Dr. Meir Daller -- \$3.8m settlement resolving allegations that physicians referred unnecessary test to a laboratory



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Drug and Medical Device Manufacturers Remain Focus Area

- Shire pharmaceuticals LLC -- \$350m to resolve allegations that it induced clinics and physicians to use or overuse its bioengineered human skin substitute
- Mylan paid \$465 m to resolve allegations that it underpaid rebates owed under Medicaid Drug Rebate program by erroneously classifying EpiPen as a generic drug in order to avoid paying higher rebates

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Post-Acute Cases Remain Focus Area

- Improper payments estimated at 11% (\$4B+/year)
- Common areas for claims against Post Acute providers
 - Medical necessity (documentation)
 - Rehab/RUG over-utilization
 - Kickbacks for referrals, especially with medical directors
 - Abuse/worthless services
 - Psychotropic meds/chemical restraints
 - "Swapping" allegations with ancillary service providers

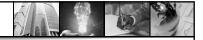
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Hospitals and Health Systems Remain Focus Area

- TeamHealth Holdings, f/k/a IPC The Hospitalists, Inc. (February 6, 2017) -- \$60 Million FCA settlement to resolve allegations that TeamHealth knowingly encouraged hospitalists to falsely bill by upcoding so that the hospital could "catch up" to peers.
- Indiana University Health/HealthNet (April 27, 2017) --\$18M settlement to resolve allegations that Indiana University Memorial Hospital provided Health/Net a free \$10M line of credit in exchange for the referral of OB/GYN patients to the hospital.

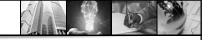
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Observations on Growth of FCA cases

- Many more law firms have joined the qui tam bar
- Government intervention stats roughly constant approx. 15-20% of cases result in intervention
- More cases proceed by whistleblower after declination
- More outsized awards of \$50+MM and even \$100+MM to relators
- Theories ebb and flow but all have theme of companies/providers that "place profits before patients"

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SOME QUESTIONS WE ARE ROUTINELY ASKED

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Questions at the Beginning of a Matter

- What's the False Claims Act? What are penalties?
- How can the government investigate me or my company?
- How does the government decide who to investigate?
- How do I know if my company is under investigation?
- Can I get a copy of the complaint? Is there a qui tam?
- Is the investigation public?

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Questions as the Investigation Gets Going

- My company got a CID or Subpoena; now what?
- Who is the qui tam relator? If still employed, what do we do?
- How long will this take?
- Seriously?
- What can we say about the case while it is under seal?
- Is this a criminal investigation?
- Will the government want to talk to employees? Do they need counsel?
- We have lawyers all over these issues, shouldn't we just waive privilege and show the work from our counsel?

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Questions as the government makes its decision

- The government decided to decline, now what?
- The government has decided to intervene, now what?
- Or...should we jump ahead of the government and try to settle?
- Do we have to point fingers? Or the corollary, could there be individual exposure
- When and what do we tell our bankers, stockholders, etc.?

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Questions if there's a settlement

- When should we settle?
- Is it public?
- Won't a settlement crush our reputation?
- Must the company admit liability?
- What if we can't pay? How does the "inability to pay" process work?
- Do we really have to pay the relator? And his or her lawyer?
- Seriously?
- Why is it so hard to get individual releases?
- How bad/onerous is a Corporate Integrity Agreement?

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Questions about Trial

- What are the odds?
- How expensive?
- If we win, is that it or can the government do other things to the company?
- Can the company make it to trial?
- Civil v. criminal what are the differences?

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What can we do to mitigate likelihood of FCA case?

- Rigorous compliance program
- Tone at the top
- Routine auditing/monitoring
- Training
- Publicity of some type on discipline
- Watch those emails! Educate on bad emails
- Follow HHS-OIG Corporate Integrity Agreements and create your own work plan from what they are doing

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