#1 Current Provider Self-Disclosures (What are other compliance officers disclosing?)

- self-referrals, Stark violations, and kickbacks (including donation of equipment, electronic health records software)
- excluded persons; unlicensed staff, unenrolled staff, expired licenses or certifications
- physician direct supervision failures
- unnecessary cardiac stent procedures (Penn settlement $845,000 1/19/17)
- no timely physician certification for plan of care, re-certifications; missing physician signatures, use of rubber stamps for ordered tests (Abington Memorial Hospital $491,000 settlement 5/27/17 for cut and paste home health signatures)
- cut and paste admitting history and patient encounter notes
- For current list, see https://oig.hhs.gov/fraud/enforcement/cmp/psds.asp
2. The Paradox of Risk Adjustment and coding intensity in Medicare Advantage.

• “Recent research has found that risk scores for MA plan members have been growing more rapidly than risk scores for FFS beneficiaries.”
• “. . . MA plan enrollees have higher risk scores than similar FFS beneficiaries because of plans’ more intensive coding efforts. . . CMS makes an across-the-board (downward) adjustment to the risk scores of MA plan enrollees to make them more consistent with FFS coding.”
• 2016 MedPac Report to Congress
• The RADV FFS Adjuster – expected error rate in coding
• “CMS estimates that 9.5% of payments to MA organizations are improper, mainly due to unsupported diagnoses submitted by MA organizations.” OIG 2017 Work Plan at 29 “Risk Adjustment Data-Sufficiency of Documentation Supporting Diagnoses” (expected issue date 2018)

3. False Reporting by health plan about health status of Medicare Advantage Plan beneficiaries

• 5/16/17 USA False Claims Complaint vs. UnitedHealth Group (second UHG case)
• “UHG conducted a national Chart Review Program designed to identify additional diagnoses not reported by treating physicians that would increase UHG’s risk adjustment payments. However, UHG allegedly ignored information from these chart reviews showing that hundreds of thousands of diagnoses provided by treating physicians and submitted by it to Medicare were invalid and did not support the Medicare payments it had previously requested and obtained.”
US ex rel Swoben v. United Healthcare
832 F. 3d 1084 (9th Cir. 2016)

• United allegedly submitted false certifications under this provision (certification that the risk adjustment data is “accurate, complete, and truthful”) in violation of the False Claims Act, by conducting retrospective reviews (of medical records provided by treating physicians) designed to identify and report only under-reported diagnosis codes (diagnosis codes erroneously not submitted to CMS despite adequate support in an enrollee’s medical records), not over-reported codes (codes erroneously submitted to CMS absent adequate record support).

Challenge by Medicare Advantage organizations to “report, refund, explain”

• overpayments United Healthcare v. Price (DCDC 3/31/2017) under 42 C.F.R. § 422.326 (report, refund, explain regulation)
• “Under the CMS Rule, any inadequately documented diagnostic code not supported by underlying medical documentation will result in an overpayment.”
• The CMS Rule requires Medicare Advantage organizations to undertake "reasonable diligence" which the agency requires "at a minimum . . . proactive compliance activities conducted in good faith by qualified individuals to monitor the receipt of overpayments."
• Specific diagnostic codes providers sent to insurers have error rates as high as 20%-in past, neither insurers nor CMS reviewed the codes sent.
• United Healthcare permitted to challenge CMS Rule; need not wait for OIG enforcement
#4- False Reporting by health care providers of invalid diagnoses to health plan

- 5/16/17 complaint “UHG allegedly knew that its financial arrangements with these providers created a strong incentive for and increased the risk of these providers to report invalid diagnoses. UHG’s own reviews of these providers’ medical records confirmed that the providers were reporting invalid diagnoses.”
- 5/2/17 intervention-UHG funded chart reviews conducted by HealthCare Partners (HCP), one of the largest providers of services to UHG beneficiaries in California, to increase the risk adjustment payments received from the Medicare Program for beneficiaries under HCP’s care.
- UHG allegedly ignored information from these chart reviews about invalid diagnoses and thus avoided repaying Medicare monies to which it was not entitled.
- How long before the first provider cases are filed?

#5 Internal Investigations after the 2015 Yates Memorandum

- “complete cooperation”
- Individual exposure
- “[s]ometimes . . . the corporate officers who caused the problem should be subjected to more severe punishment than the stockholders of the company who didn’t know anything about it.” AG Sessions at his confirmation hearing.
The Yates Memo-2015

• For a corporation to be eligible for cooperation credit, corporation must provide to DOJ “all relevant facts” “about individuals involved in corporate misconduct.”

• Prosecutors are directed to pursue senior individuals criminally and civilly even after criminal resolution for corporation.


Yates Memorandum
DOJ Process-9-28.700

• In order for a company to receive any consideration for cooperation under this section, the company must identify all individuals involved in or responsible for the misconduct at issue, regardless of their position, status or seniority, and provide to the Department all facts relating to that misconduct. If a company seeking cooperation credit declines to learn of such facts or to provide the Department with complete factual information about the individuals involved, its cooperation will not be considered a mitigating factor.
Yates Memorandum
DOJ Process-9-28.720

• the company may be eligible for cooperation credit regardless of whether it chooses to waive privilege or work product protection in the process, if it provides all relevant facts about the individuals who were involved in the misconduct. But if the corporation does not disclose such facts, it will not be entitled to receive any credit for cooperation.

Yates Memorandum
DOJ Process-9-28.710

• Many corporations choose to collect information about potential misconduct through lawyers, a process that may confer attorney-client privilege or attorney work product protection on at least some of the information collected. Other corporations may choose a method of fact-gathering that does not have that effect—for example, having employee or other witness statements collected after interviews by non-attorney personnel. Whichever process the corporation selects, the government's key measure of cooperation must remain the same as it does for an individual: has the party timely disclosed the relevant facts about the putative misconduct?
Corporate Response to Yates investigation

• Question: VP of Finance states to outside counsel that diagnosis data submitted to managed care entities and Medicare was probably not accurate—the consulting firm told him they only looked for chart information that would result in an upcode, and was paid on a contingency basis for successful upcodes. What is the “factual” information in this admission? How should the company provide this information?

Yates Memorandum-Corporate Response and Remediation-9-28.1000

• “Among the factors prosecutors should consider and weigh (in deciding whether to prosecute the corporation) are whether the corporation appropriately disciplined wrongdoers, once those employees are identified by the corporation as culpable for the misconduct.
• “Effective internal discipline can be a powerful deterrent against improper behavior by a corporation’s employees. Prosecutors should be satisfied that the corporation’s focus is on the integrity and credibility of its remedial and disciplinary measures rather than on the protection of the wrongdoers.
• “(a) corporation’s quick recognition of the flaws in the (compliance) program and its efforts to improve the program are also factors to consider as to the appropriate disposition of a case.
Corporate Response to Yates investigation

• Question: Should the corporation discipline an employee whose cooperation is needed in an investigation? Should it be public in its discipline?

#6: What has happened in Yates prosecutions?

• Acclarent, Inc. medical device company $18 million False Claims Act civil settlement.
• CEO William Facteau, VP Sales Patrick Fabian acquitted of felony charges, convicted of misdemeanors relating to unlawful distribution of medical devices.
#6: What has happened in Yates prosecutions?

- Warner Chilcott-specialty drug manufacturer-guilty plea, $22 million criminal fine and $102 million settlement for kickbacks to physicians.
- Carl Reichel, president, acquitted of single count of conspiracy.
- District managers entered guilty pleas.
- Physician charged with accepting kickbacks ($23,500 in meals and speaker fees) (case pending).

#6 What happens in Yates investigation?

- United States ex. rel. Drakeford v. Tuomey Healthcare Systems- $72.4 million
- $237 million judgment after trial (2013)
- Ralph J. Cox, CEO, and Gregg Martin, VP depart (2013)
- Affirmed by appeals court (8/2015): concurring judge: “This case is troubling. It seems as if, even for well-intentioned health care providers, the Stark Law has become a booby trap rigged with strict liability and potentially ruinous exposure—especially when coupled with the False Claims Act.”
- False Claims settlement of judgment 10/2015 $72.4 million payment
- Tuomey sold to Palmetto Health 1/1/2016
- Tuomey required to retain an independent review organization to monitor any arrangements it makes with physicians or other sources of referrals for the duration of the five-year Corporate Integrity Agreement.
- Malpractice suit TUOMEY v. NEXSEN PRUET, LLC (copy of complaint attached)
- Ralph J. Cox, III (Sept. 2016) – former CEO- and Board Member
  - Personal $1 million settlement agreement & 4 years’ exclusion from federal programs
  - Cox agreed to fully cooperate with the DOJ’s ongoing investigation of other individuals and entities associated with the Tuomey case.
  - “Entities engage in fraud because of actions by individuals and OIG will continue to identify and take administrative enforcement actions against such individuals.” OIG chief counsel
#7 OIG patient dumping investigations resulting in sanctions this year

- Covenant Medical Center (Iowa)(psych)
- Cape Fear Medical Center (NC)(labor)
- Phoebe Putney Memorial (GA)(urology transfer)
- Belton Regional Med Center (MO) (psych)
- Twin Cities Hospital (FL) (unstable patient redirected)
- 9 other hospitals since June 2016. [https://oig.hhs.gov/fraud/enforcement/cmp/cmp-ae.asp](https://oig.hhs.gov/fraud/enforcement/cmp/cmp-ae.asp)
- New staff at OIG for administrative prosecutions

#8 Data Driven Investigations

- OIG's Consolidated Data Analysis Center
- Lab cases-genetic, pharmacogenetic testing, urine drug testing
- Discharge vs. post-acute care transfer for home health services (Midstate Medical Center $436,000, Hartford Hospital $2.4 million (Ct)),
- “new patient evaluation and management” vs. “established patients” (UCSF $1.4 million))
#9 CODE MANIPULATION
THE HOW-TO CASE

- addition of modifiers 25 (significant separate E&M service same day), 59 (significant separate same day non-E&M service) or 91 (same lab test, same day) to CPT codes;
- billing of G0 codes (multiple visits, same day for unrelated conditions) codes;
- edit evasion by unbundling of previously denied claims;
- Deleting accident and injury information to obtain payment for denied claims;
- Resubmitting Medicare claims without accessing underlying clinical documentation or communicating with coders to ensure that changes were clinically warranted;
- Altering discharge status indicators to “discharge to home”;
- As alleged in plaintiff’s complaint in US EX REL. WORTHY v. EASTERN MAINE HEALTHCARE SYSTEMS AND ACCRETIVE HEALTH (US District Court Maine 1/18/2017);

http://scholar.google.com/scholar_case?case=1422765947325695957&q=accretive+false+claims+worthy&hl=en&as_sdt=6,33&as_ylo=2013

#10 Universal Health Services, Inc., v. U.S. et al., ex rel. Escobar et al.

- June 2016 Supreme Court decision;
- Implied certification can give rise to False Claims Act (FCA) claim;
- Regulations need not be specific conditions of payment for FCA (supervised services);
- “. . . Even if a regulation is expressly designated a condition of payment, “ not necessarily liability under FCA;
- Misrepresentation must be material to payment decision;
- US ex rel. Escobar v. UNIVERSAL HEALTH SERVICES, 842 F. 3d 103 (1st Cir. 2016) Court of Appeals reversed dismissal in November, sent cases back to District Court.
- US ex rel Petratos v. Genentech (3d Cir. 5/1/17)-allegation of concealment of side effects of oncology drug insufficient for FCA claim.
FALSE CLAIMS CASES CAN LAST FOREVER

• FCA Statute of Limitations-six years from claim to file complaint
• Average FCA case time under seal-about two years
• USA ex rel. Gohil v. Aventis (off-label marketing of Taxotere)
  – FCA case filed in 2002 under seal
  – Filed wrongful termination action in NJ (settled 2005)
  – FCA case unsealed 9/2006
  – Still pending 2017

Thank you for your attention and for the opportunity to come back each year!

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