ENFORCEMENT ISSUES TO KNOW ABOUT IN 2018

HCCA Enforcement Conference 10/17
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A little about the New York Attorney General . . .

"OUR JOB AS A REGULATOR ISN'T JUST TO GO OUT AND CATCH BAD GUYS, IT'S ALSO TO HELP THE GOOD GUYS CONDUCT THEIR BUSINESS EFFICIENTLY AND EFFECTIVELY."

New York State Attorney General
Eric T. Schneiderman

1) TUOMEY-Suicide by Stark

• 2005- deal with physicians
• 2009-False Claims Stark complaint filed by physician
• 2013 jury verdict vs. Tuomey $37 million in false claims, $237 million total; Ralph J. Cox, CEO, and Gregg Martin, VP depart;
• 2013-South Carolina AG: no indemnification by hospital for Tuomey trustees and officers (Exhibit 1 to presentation)
• 2015-United States ex. rel. Drakeford v. Tuomey Healthcare Systems- $72.4 million payment
• 2015-Tuomey sold to Palmetto Health, a multi-hospital healthcare system
• 2015-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. (Exhibit 2)
• 2016-Ralph J. Cox—$1 million settlement agreement & 4 years' exclusion from federal programs -
  - ignored "red flags" raised by attorney regarding contracts
• 2016-Tuomey sues law firm Nexsen Pruet for $116 million for malpractice (March 2017 DSC opinion Exhibit 3)
2) RUCKH (CMC II LLC)

[Image]

Ruckh Verdict-MDS coding fraud

• USA ex rel. Ruckh vs. CMC II and Salus Rehabilitation LLC (MD Fla.)
• Qui Tam whistleblower case declined by both state and federal prosecutors
• Relator was nurse for 5 months in two facilities—alleged “flagrant upcoding” of Minimum Data Sets and false statements by 53 nursing homes, most of which she never visited
• Jury single damages $115 million—trebled by Judge to $347 million
• 446 false claims—penalty of $5500 per claim

The Ruckh Verdict-proof by statistical sampling

• Statistical sampling and projection (4/28/15) “Ruckh alleges that individually analyzing each claim from each of the 53 facilities is impractical” and moves to introduce statistical sampling evidence. Held: “no universal ban on expert testimony based on statistical sampling applies in a qui tam action.”
• Stay of execution on judgment conditioned on financial transparency
The Ruckh Verdict-

- Six years from filing to verdict
- 12/2016 opinion denying summary judgment characterized plaintiff’s evidence: “a broad charge and equivocal and scant evidence.”
- 31,000 pages of medical records excluded for failure to comply with discovery
- Late production, even if not willful demonstrated “careless disregard for the discovery process.”

3) Managed Care: Attestation to CMS

- The MA Organization has reported to CMS for the period of January 1, 2013, to December 31, 2013, all risk adjustment data (inpatient hospital, outpatient hospital, and physician) available to the MA Organization or PACE Organization as of January 31, 2015, with respect to the above-stated MA and MA-PD plans. Based on best knowledge, information, and belief as of the date indicated below, all information submitted to CMS in this report is accurate, complete, and truthful.
  - /s/________________________

3) FALSE ATTESTATIONS

- OIG issued reports concluding that the health risk scores for 45 percent of the beneficiaries in the California audit and 43 percent of the beneficiaries in the Texas audit were invalid because the diagnoses were not supported by the beneficiaries’ medical records or were uncertain or unconfirmed diagnoses.
- DOJ 5/17 Complaint filed in
- UNITED STATES OF AMERICA ex rel. BENJAMIN POEHLING v. UNITEDHEALTH GROUP, INC
DATA ATTESTATIONS: CMS - We don’t believe your data, so we will build in an adjustment MCOs (and AQR, and bonuses)

• “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)

4) We don’t believe your data, but . . .

• 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.”

4) We don’t believe your data, but . . .

• 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). US ex rel Swoben v. United Healthcare 832 F. 3d 1084 (9th Cir. 2016)
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?

Attestation to Health Plan

- HAP has reported to CMS during the period of (INDICATE DATES) all (INDICATE TYPE - DIAGNOSIS/ENCOUNTER/RISK ADJUSTMENT) data available to HAP with respect to HAP’s Medicare Advantage plans. Based on best knowledge, information, and belief as of the date indicated below, all information submitted to HAP, which HAP in turn relied on or submitted to CMS, is accurate, complete, and truthful.
- /s/____________________

5) Challenge to CMS “Report, Refund, Explain (6402) 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 by treating providers have error rates as high as 20%-in past, neither insurers nor CMS reviewed the codes sent.
- United Healthcare permitted to challenge CMS “reasonable diligence” Rule; need not wait for OIG enforcement
- No stay for CMS on administrative review action
6) USA ex rel Worthy. CREDIT BALANCE/ CODE MANIPULATION
THE HOW-TO CASE

• Submission of Quarterly Medicare Credit Balance report "knowingly omitting the overpayments" discussed below
• 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=14227656947326959857&q=accretive+false+claims+worthy&hl=en&as_sdt=6,33

7) 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.

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."
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.

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).

8) OIG-Report, Refund, Explain- Self-Disclosures

• excluded persons; expired licenses or certifications; unlicensed staff
• physician direct supervision and “incident to” failures
• self-referrals, Stark violations, and kickbacks (including donation of equipment, electronic health records software)
• Automatic addition of 59 and 91 modifiers (Hermann Hospital Texas $5,652,000 10-18-2016)
• Problem signatures
• https://oig.hhs.gov/fraud/enforcement/cmp/psds.asp
8) OIG- patient dumping investigations resulting in sanctions

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

9) 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))

10) Secret Probations

- Law-making through CIAs, deferred prosecution agreements (DPAs) and Non-Prosecution Agreements (NPAs) (see Teva Pharmaceuticals DPA 12/16) expectations for cooperation and assistance, Attachment A admissions “Teva hereby agrees and stipulates that the following information is true and accurate”)  
- Pharmaceutical Technologies, Inc. NPA (pharmacy benefits management firm-cooperated against president who was convicted) (agreement not available to public)
- guidance for implementing compliance requirements “pertaining to the retention and oversight of all agents and business partners.”
- mandatory due-diligence actions before entering into a relationship with a third party.
Thank you for your attention

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