

1

HEALTH LAW YEAR-IN-REVIEW

Health Care Compliance Association
Kansas City Regional Conference
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2

Agenda

- Health Care Enforcement Landscape
- False Claims Act Developments
- 60-Day Overpayment Final Rule
- OIG Advisory Opinions
- HIPAA Enforcement
- Ransomware and Other Cybersecurity Issues
- Questions?

3

HEALTH CARE ENFORCEMENT LANDSCAPE

4

2016 YTD Statistics

- Government recovered \$2.7 billion in improper payments from federal healthcare programs in first half of 2016
 - \$554.7 million from audits
 - \$2.22 billion from investigations
- Recoveries up over \$1 billion from first half of 2015

5

Enforcement Trends

- June 22, 2016 Take Down
 - Largest in History
 - Nationwide sweep led by the Medicare Fraud Strike Force in 36 federal districts resulting in criminal and civil charges against 301 individuals, including 61 doctors, nurses and other licensed medical professionals
- Focus on Individual Responsibility
- Focus on Medical Necessity (Skilled Nursing Facilities, hospice)

6

FALSE CLAIMS ACT DEVELOPMENTS

7

Increase in FCA Penalties

- On June 30, 2016, the Department of Justice released its interim final rule making inflationary adjustments to civil monetary penalties under its jurisdiction, including those authorized by the False Claims Act
- Minimum penalty amount now \$10,781 per claim; the maximum penalty \$21,563 per claim
- Effective August 1, 2016, but will apply only to violations occurring after November 2, 2015

8

Settlement Trends

Kickback cases

- Continuing to see cases involving kickbacks, particularly in context of speaker engagements
- Also charges brought against individuals, including physician, for accepting bribes in exchange for referrals

Ambulance Companies

- Multiple cases of ambulance companies settling allegations of submitting ambulance transportation claims not meeting Medicare requirements for emergency transport
- Twelve OIG Civil Monetary Cases 2015-2016 resulting in recoveries over \$1.9 million

9

Settlement Trends, Cont.

Laboratories

- Enforcement activities involving test referrals

Employment of Excluded Individuals

- CardioSpecialists Group, Ltd paid \$274,721 to OIG to resolve allegations that CSG employed an excluded individual as a medical biller.
- Cascadia Behavioral Health, Inc. settlement allegations for \$92,052

10

Interesting Settlements

Salix Pharmaceuticals

- \$54 million settlement in a civil fraud lawsuit against Salix, specialty pharmaceutical company. Allegations involved illegal kickbacks to doctors through "speaker programs" to induce them to prescribed Salix products

21st Century Oncology

- National chain of cancer clinics agreed to pay \$35 million to end a False Claims Act suit alleging fraudulent billing for unreliable radiation measurements.

11

Interesting Settlements, Cont.

Respironics

- Respironics agreed to pay \$34.8 million to resolve FCA allegations it paid kickbacks in the form of free call center services to DME suppliers that bought its masks for patients with sleep apnea.

Olympus

- \$623.2 million settlement resolving criminal and civil claims related to kickback scheme, settling claims under FCA and Foreign Corrupt Practices Act (FCPA)

12

Interesting Settlements, Cont.

Kindred Care / RehabCare

- Agreed to pay \$125 million to settle whistleblower suit claiming Kindred caused the submission of false claims to Medicare for rehabilitation therapy
- Allegation that therapy was either unnecessary or not provided

Noteworthy Court Decisions

Universal Health Services Inc. v. U.S. ex rel Escobar

- June 16, 2016 unanimous Supreme Court decision
- Defendant can face False Claims Act liability under an implied certification theory where:
 - (1) The claim asserts a request for payment and makes specific representations about the goods and services provided; and
 - (2) failure to disclose noncompliance with *material* statutory, regulatory, or contractual requirements makes those representations misleading half-truths.

Noteworthy Court Decisions

Warner Chilcott

- October 2015: Warner Chilcott agrees to plead guilty to felony health care fraud scheme and pay \$125 Million to resolve criminal liability and False Claims Act allegations
- Proceedings against district managers and former president for participating in kickback scheme of bribing doctors through meals and speaking fees followed
- June 2016: Federal jury acquitted the former President

Noteworthy Court Decisions

U.S. v. AseraCare

- Government alleged AseraCare knowingly billed for hospice services for patients who were not eligible for hospice
- District Court for the N. District of Alabama threw out jury verdict for government, ordering new trial on basis of jury instructions into falsity requirement under the False Claims Act, stating: "**[A] mere difference of opinions among physicians, without more, is insufficient to show falsity.**"
- March 2016 Court granted summary judgment to AseraCare, finding government offered no evidence beyond its own expert's opinion
- Government has filed a notice of appeal

16

60 DAY OVERPAYMENT RULE

17

60 Day Final Rule

- February 12, 2016: CMS published the Reporting and Returning of Overpayments Final Rule
- Final Rule took effect on March 14, 2016
- Key Themes:
 - Providers must report and return overpayments within 60 days of the date of identification
 - An overpayment is not identified until it is quantified
 - Reasonable diligence to identify overpayments starts with "credible information" that an overpayment may exist and should take no more than six months
 - The lookback period is six years

18

OIG ADVISORY OPINIONS

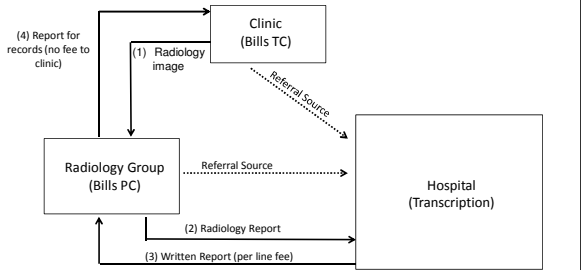
OIG Advisory Opinion 16-02

- Proposal by academic medical center to offer pregnant women free transportation to/from hospital and short-term lodging
 - Mileage reimbursement or public transport reimbursement
 - Lodging only per physician order (at a leased apartment building with 12 rooms)
- Implicates anti-kickback statute and civil monetary penalties laws
- Favorable opinion – no administrative sanctions

OIG Advisory Opinion 16-02

- Favorable facts
 - No advertising
 - Only available to existing clinic patients
 - Patient benefits (continuity of care)
 - “Modest” transportation and lodging
 - Offered to all patients, irrespective of payor
 - No shifting costs to payors
 - State oversight (AMC is state-owned; Medicaid and CHIP population)

OIG Advisory Opinion 15-15



OIG Advisory Opinion 15-15

- Hospital bills radiology group for transcription; clinic pays \$0 to radiology group or hospital
- Previous AO: transcription costs are the responsibility of the radiology group
- No remuneration from hospital to clinic
 - Hospital expects to get paid by someone
- No remuneration from radiology group to clinic
 - Up to parties to decide who pays – because both are reimbursed as part of the PC and TC.

HIPAA ENFORCEMENT

HIPAA Enforcement

- *Lincare, Inc., d/b/a United Medical* (\$239,800 CMP)
 - Employee provided in-home patient services
 - Left the records in her home
 - Husband impermissibly accessed 278 records
 - Husband complained to OCR
- OCR
 - Failure to safeguard PHI
 - Failure to develop policies on PHI removed from offices

25

HIPAA Enforcement

- *North Memorial Health Care of Minnesota* (\$1,550,000 settlement)
 - Laptop stolen from business associate workforce member's vehicle (9,497 individuals' PHI)
 - BA had access to database of 289,904 patients
 - OCR
 - No Business Associate Agreement in place
 - No enterprise-wide security risk analysis

26

HIPAA Enforcement

- *Raleigh Orthopaedic Clinic, P.A.* (\$750,000 settlement)
 - Disclosure of x-rays and other films to silver harvesting vendor (17,300 individuals)
 - OCR
 - No BAA
 - "It is critical for entities to know to whom they are handing PHI and to obtain assurances that the information will be protected."

27

HIPAA Enforcement

- *Feinstein Institute for Medical Research* (\$3,900,000 settlement)
 - Laptop stolen from employee vehicle (13,000 individuals' PHI)
 - OCR
 - Limited security management process
 - Lacked policies/procedures governing removal of laptops
 - Lacked policies for authorizing access to ePHI; unauthorized users; and procurement process

28

HIPAA Enforcement

- *University of Mississippi Medical Center* (\$2,750,000 settlement)
 - Breach of unsecured ePHI (laptop stolen by visitor) (10,000 individuals)
 - OCR
 - UMMC was aware of risks/vulnerabilities (dating back to 2005)
 - No significant risk management
 - Failure to notify affected individuals (did notify through media and website)

29

HIPAA Enforcement

- *Advocate Health Care Network* (\$5,500,000 settlement)
 - 2013 breaches involving stolen desktop computers; breach by BA; and lost laptop (4M individuals' PHI)
 - OCR
 - Failure to conduct thorough risk analysis and implement safeguards
 - No BAA with vendor where breach occurred

30

HIPAA Enforcement

- *Oregon Health & Science University* (\$2,700,000 settlement)
 - Lost laptops and thumb drive; storage of ePHI at vendor without BAA
 - OCR
 - Widespread vulnerabilities
 - Mitigation not timely
 - Lacked policies/procedures for encryption

31

HIPAA Enforcement

- New York Presbyterian Hospital (\$2,200,000 settlement)
 - Filming of "NY Med" ("egregious" disclosure of 2 patients' PHI)
 - OCR
 - Did not obtain patients' authorization
 - Failure to safeguard PHI (allowing film crew unfettered access to the facility)

32

RANSOMWARE AND CYBERSECURITY

33

Cyber War



The screenshot shows the NORSE interface with a world map. On the left, under 'ATTACK ORIGINS', a list of countries is shown with a 'COUNTRY' column. On the right, under 'ATTACK TARGETS', a list of countries is shown with a 'COUNTRY' column. The map displays lines connecting various countries, representing network connections or attack paths.

The Cybersecurity Landscape

- KPMG survey:
 - 4 out of 5 health care organizations have experienced a cyber attack
 - Less than half of the executives surveyed say their organizations are prepared
 - Greatest vulnerabilities:
 - External attackers
 - Sharing data with third parties
 - Employee breaches
 - Wireless computing

Here's How It Begins...

From: <Name of executive / CEO / CFO> <corporate email address>
 Reply-To: <Name of executive / CEO / CFO> <non-corporate email address>
 To: <Targeted victim in HR / Finance>
 Subject: SALARY REVIEW

Hello

Kindly send me the 2015 W-2 (PDF) of all our company staffs for a quick review

Thanks

It Looks Legitimate

From: IRS Online <irs@irs.gov>
 Reply-To: "irs@irs.gov" <irs@irs.gov>
 Date: Thursday, April 11, 2013, 12:13 PM
 Subject: Final reminder: Notice of Tax Return ID: 13H583326/13



04/11/2013
 Reference: 13H583326/13
 Claim Your Tax Refund Online

Dear Taxpayer,

We identified an error in the calculation of your tax from the last payment, amounting to \$ 319.95.

In order for us to return the excess payment, you need to create a e-Refund account after which the funds will be credited to your specified bank account.

From: IRS "Get Started" below to claim your refund.
[Get Started](#)

Link has nothing to do with IRS (or IRS.gov)

37

Here's How It Ends...



The image shows two screenshots of news articles. The left screenshot is from Billboard.com, titled "Grand Ole Opry Parent Company Falls Victim to Phishing Scam". The right screenshot is from Ars Technica, titled "Payroll data leaked for current, former Snapchat employees". Below the screenshots is a graphic of a speech bubble containing a dollar sign and a question mark.

38

2016 – Year of “Whaling”

- Continuing surge in cyber attacks across many industries
- Hackers' tactics are constantly evolving
- Now targeting the big “phish”
 - Senior executives and board members
 - Example: E-mail to CEO with notification of a subpoena
 - E-mail includes link or PDF
 - One click = Malware; takes control of computer

39

SMS Spoofing / Social Engineering Example

- Through social media, hackers find [fill in the blank]'s cell phone
- Hackers also find his/her assistant's cell phone
- Can send a text from boss to assistant (in assistant's phone, it comes up as from the boss) saying: he/she needs the assistant to send the all claims from 2015 file to XYZ who has been hired by Blue Cross Blue Shield. Urgent. Don't call me or text me back because I'm in an important meeting.
- What do you think happens?

40

Ransomware Attacks

- *Hollywood Presbyterian Med Ctr. (FL)*
 - Attack resulted in lockdown of computer systems (including electronic health records)
 - Hospital declared state of emergency
 - Paid ransom (40 Bitcoins ≈ \$17,000)
 - No evidence patient or employee information was accessed

41

Do We Pay The Ransom?

- Is it the cheapest option?
- Will paying "pay off"?
- How big is the gap in time?
- Decision will based on the specific circumstances
 - Is there a backup recovery strategy?
 - How long will it take?

42

HIPAA At Your Facility

- What needs to be addressed **now**?
 - Lack of updated policies/procedures
 - Failure to identify and address basic risks
 - Outdated, unsupported software
 - Lack of encryption
 - Inconsistent/incomplete efforts to remediate risks

HIPAA – What to Do Now?

- Budget for ongoing HIPAA compliance
- Know and **follow** policies/procedures
- Training/awareness
- Audit access
- Ongoing privacy and security risk assessments

Questions



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Kelly Schulz believes in a practical approach to addressing each client's business outcomes and objectives in a timely and efficient manner. She assists a broad range of health care organizations in criminal and civil investigations and regulatory compliance matters, and draws from this experience to assist clients with:

- Conducting investigations regarding potential violations of various civil, criminal, and administrative laws, including the False Claims Act and the Foreign Corrupt Practices Act
- Responding to government inquiries and subpoenas
- Assessing whistleblower allegations
- Performing due diligence in connection with corporate transactions

Prior to joining Polsinelli, Kelly practiced laws for over three years abroad, and she is easily attuned to the importance of understanding the nuances of each unique client's needs.



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Michael Chase is a partner at Baird Holm LLP in Omaha, Nebraska. Mr. Chase serves as counsel to a variety of health care clients on Federal and State regulatory matters including:

- The federal health care fraud and abuse laws
- HIPAA and Meaningful Use
- Compliance programs, investigations
- Medical staff matters
- Clinic research and institutional review board compliance

Mr. Chase is also a member of Baird Holm's Privacy and Data Protection Group and counsels clients on data breach response/notification, incident response plans, and data security preparedness.
