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## Stump a Health Care Lawyer: Get Those Questions Ready!

Vickie B. Ahlers  
Andrew D. Kloeckner  
Kimberly A. Lammers  
Baird Holm LLP

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## 2018 HIPAA Update



"No, it's not a female Hippopotamus, anyone else know?"

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## Civil Monetary Penalties

- *MD Anderson Cancer Center (\$4.3M)*
  - 3 data breach reports (loss of unencrypted laptop and USB drives)
  - Had encryption policies dating back to 2006
  - Risk analysis identified encryption as high risk
  - But, failed to encrypt inventory of devices
  - MDA tried to argue PHI was for "research" and not subject to HIPAA's non-disclosure requirements (ALJ disagreed)
  - 2nd largest summary judgment in OCR's history

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## OCR Resolution Agreement

- *Fresenius Medical Care North America* (\$3.5M settlement)
- Five breaches from 2/23/12 to 7/18/12
  - Unauthorized access for no purpose
  - Failure to implement p/p for security incidents
  - Failure to implement p/p for receipt/removal of hardware and electronic media (and movement within the facility)
  - Failure to protect from tampering and theft
  - Failure to encrypt PHI

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## OCR Resolution Agreement

- *21st Century Oncology* (\$2.3M settlement)
- On 2 occasions, FBI notified 21CO that PHI was illegally obtained by third party
- 2,213,597 affected individuals
- Failure to implement security measures
  - Including audit logs, access reports, security incident tracking reports; and disclosures to third party vendors without a BAA

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## Common Theme

**"FAILED TO CONDUCT AN ACCURATE  
AND THOROUGH RISK ANALYSIS OF  
POTENTIAL RISKS AND VULNERABILITIES TO  
THE CONFIDENTIALITY, INTEGRITY, AND  
AVAILABILITY OF ALL ITS EPHI"**



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## OCR Resolution Agreement

- Most recent resolution – Sept. 20, 2018
- Boston Medical Center, Brigham and Women's Hospital and Massachusetts General
  - (3 separate settlements totaling \$999K)
- Allowed ABC access to premises to film documentary series without authorization from patients
- From the press release: "On January 26, 2015, HHS initiated a compliance review of BMC based on information contained in a Boston Globe article dated January 12, 2015. The article indicated BMC permitted ABC News to film a medical documentary program at BMC."

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## 42 C.F.R. Part 2 (Substance Abuse Records)

- Jan. 2018: first major, substantive revision in 30+ years
- Disclosures for payments and health care operations purposes
- Disclosures for audit and evaluation
- Prohibition on re-disclosure (new, abbreviated notice)

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## Stark Update *WINTER IS COMING . . .*



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## Stark Update

- Bipartisan Budget Act (2/9/18) modified the Stark statute to implement 2 previous informal clarifications
  - Written Requirement: can be met by a collection of documents, including contemporaneous documents evidencing the course of conduct
  - Signature Requirement: can be met if, within 90 days of when the arrangement became noncompliant, the parties obtain the required signatures

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## Stark Update

- CY 2019 Physician Fee Schedule (7/12/18)
  - Proposes regulations that mirror statutory language passed by Congress in the BBA
  - "Special Rule on Compensation" at 42 CFR 411.354(e)
    - "arrangement" can be a compilation of documents
  - "Temporary Noncompliance with Signature Requirements" at 42 CFR 411.353(g)
    - 90 days to obtain signatures
    - No longer limited to using this exception once every 3 years
    - Retroactive to 2/9/18

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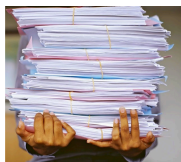
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## Stark Update

- CMS to review Stark Law
  - Will form inter-agency working group
  - Part of CMS "Patients Over Paperwork" initiative
  - Effort to "de-regulate" health care and lift burdens on providers
  - Substantive changes in the short term not likely – so continue to ensure that all current and future arrangements (for now) comply!



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## Fraud and Abuse Update



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## FY 2018 Statistics

- October 2017 – March 2018
- OIG anticipates expected investigative recoveries of over \$1.46 billion
- FY17 recoveries: \$4.13 billion
  - 881 criminal actions (↑)
  - 826 civil actions (↑)
  - 3,244 excluded individuals and entities (↓)
- FY17 State Medicaid Fraud Units (May 2018): \$1.8 billion in recoveries

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## OIG Semiannual Report to Congress: Highlights

- 61% of Medicare claims for outpatient physical therapy did not comply with medical necessity, coding, or documentation requirements
- Opioid epidemic; leveraging data to identify abusers
- The Female Pelvic Medicine Institute of Virginia, P.C.
  - Allegation: Services provided by unqualified individuals, billed CPT codes improperly, and improper supervision for "incident to" services
  - Nathan Guerette, M.D.; \$1.4 million settlement and 3-year Corporate Integrity Agreement (CIA)
  - Worked in collaboration with Consolidated Data Analysis Center (CDAC)

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## OIG Advisory Opinion 18-03

- FQHC look-alike (Provider) provides IT items and services, without charge, to a county health department
  - Laptop, webcam, microphone, video software, maintenance/update (remuneration)
- Purpose is to facilitate telemedicine encounters related to HIV prevention
- County could serve as a referral source to Provider
- Favorable opinion – low risk of fraud and abuse
  - Safeguards to prevent patient steering
  - Telemedicine items would not limit or restrict flow of info
  - Unlikely to inappropriately increase costs to Federal programs
  - Primary beneficiaries would be County Clinic patients

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## OIG Advisory Opinion 18-05

- Hospital established caregiver center to provide or arrange for free or reduced-cost support services to caregivers
  - Resource library, educational sessions, equipment lending (iPod), free respite care while caregivers are attending sessions
- Is this likely to influence caregivers to select the Hospital for reimbursable services?
- Not protected by the "Access to Care" or "Financial Need-Based" exceptions; but no sanctions
  - Primarily benefits caregivers (not care recipients)
  - Available to all caregivers
  - Not marketed
  - Does not increase costs to Federal health care programs

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## MPFS Proposed Changes

- CMS believes E/M documentation guidelines should be revised to:
  - reflect current practice patterns
  - reduce administrative and audit burden
  - take into account EMRs/technology advancements
- Considering basing visit levels only on MDM and/or time
- CMS estimates proposed changes will save approximately 51 hours of time for each clinician per year
- CMS Administrator Seema Verma: "If we're serious about improving the quality and access for patients, we have to address the concerns of providers on the front lines"

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### Ground Rules

- Please do not share confidential or identifiable information
- This is intended to be for education purposes only
- This is not legal advice
- Your questions and our responses do not create an attorney-client relationship



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## Ground Rules



- We may "phone a friend" i.e., ask other Baird Holm attorneys in the audience to take a question
- Baird Holm swag is available for those who ask questions (while supplies last!)

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## Questions



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