Health Law
Year-In-Review

Iowa HFMA
January 17, 2019

Michael W. Chase
Abigail T. Mohs
Agenda

• Year (or so) – in – review of current “hot” topics
  – Industry news
  – Program updates
  – Enforcement examples
• Exercise in issue spotting
• Strategies and best practices
Fraud and Abuse
Settlement Trends

Medicaid Fraud

– Five-physician practice in New York paid $750,000 to settle allegations it billed NY Medicaid for services provided by unenrolled providers and performed services without proper supervision; whistleblower received 18% of settlement

– Nevada health care provider created false records and progress notes for Medicaid beneficiaries and submitted claims to Nevada Medicaid; sentenced to 364 days in jail

– MassHealth paid $4 million to settle allegations that it employed unlicensed individuals to provide mental health services
Settlement Trends

Anti-Kickback Statute

– Home health agency entered into sham physician employment and medical director contracts to disguise illegal kickbacks; Owner-COO sentenced to almost 7 years in prison and $16 million in restitution to Medicare

– IU Health provided interest-free line of credit to Indiana’s largest FQHC; the credit balance routinely hovered around $10 million; Government alleged illegal remuneration in exchange for FQHC’s OB/GYN patients

– CEO and two marketing and sales employees convicted in federal court for paying between $10-$17 dollars in “handling fees” to physicians for each patient referred to one of two laboratories; nearly $115,000,000 judgment under FCA
Settlement Trends

Stark Law

- *Qui tam* suit alleged two New York hospitals entered into compensation arrangements and leases in violation of Stark; settled claims for $4 million

- Meadows Regional Medical Center in Vidalia, Georgia settled alleged Stark and anti-kickback violations for $12.8 million; DOJ highlighted Meadows’ cooperation in press release
Settlement Trends

Stark Law

– Los Angeles hospital allegedly paid above-market rates to rent office space in physicians' offices and had improper marketing arrangements ($42M)

– Operator of cancer centers paying physicians excessive compensation ($26M)
But...the closing was "in no way related" to the $42M settlement.
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
  - Iowa: 354 investigations; ~$4.8 million total recoveries
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
(Light) Stark Update

• CY 2019 Physician Fee Schedule (11/1/18)
  – Regulations that mirror statutory language passed by Congress in the Bipartisan Budget Act of 2018
  – "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
Another Stark Update Soon?

• 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 the gov't generally) 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!
CMS/OIG Requests for Information (RFI)

- CMS & OIG release RFIs in June and August, 2018, respectively
  - CMS: Stark Law (83 FR 29524)
  - OIG: Anti-Kickback Statute (AKS) (83 FR 43607)
- Essentially: What changes can we make to Stark & AKS in order to realize goal of the triple aim (i.e., improved patient experience, improved health of populations, and lower costs)?
The structure of arrangements between parties that participate in alternative payment models or other novel financial arrangements designed to promote care coordination and value

The need for new or revised safe harbors (AKS), exceptions to "remuneration" (CMP), and exceptions (Stark) to promote beneficial care coordination, patient engagement, and value-based arrangements

Terminology and definitions related to APMs, value-based arrangements, and care coordination

#1

#2

#3
RFIs: Sample Requests

- Current or proposed innovative/novel arrangements for care delivery models
- Current regulations prohibiting such models; alternatively, propose regulations permitting such models
- Definitions for important terms (e.g., APMs, risk, risk-sharing, coordinated care, care coordinator, clinical integration, etc.)
- Defining "commercial reasonableness" or modifying definition of "FMV"
- Cybersecurity
Comments on Stark

• New regulatory exceptions
  – Value-based initiatives
  – Data analytics software to achieve care coordination

• Add protections for coordination among care team
  – Reward for outcomes primarily facilitated from other members of the care team (i.e., social workers, dieticians, APNs)

• Burden of compliance
  – AHA estimates ~$20,000 per contract (includes FMV opinion)
  – Midwest health system estimates annual compliance costs at approximately $4 million
  – HSSR: Greater complexity, increased compliance costs
Comments on Stark, cont.

• APMs or novel financial arrangements often abandoned due to Stark concerns
• Define common terms
  – Commercial reasonableness, FMV, referral, signed by the parties, compensation arrangement
• Takeaway: Stark created for FFS world and requires updating for new innovative payment models
Comments on AKS & CMP

• Adopt new safe harbors
  – Value-based arrangements
  – Permit activities that address "social determinants of health"
    – Rural health care
• Permit any item or service transferred for below FMV if based on financial need
• Care coordination for all provider types
  – Hospital systems v. solo hospitals
Comments on AKS & CMP, cont.

- Increase "nominal value" annually for CMP
  - Currently: $15/$75
  - Texas Health Resources: Uber rides exceed $15
- Cybersecurity
  - Interconnected providers share information & liability for security threats
  - Larger institutions connecting to smaller
- Safe harbor incorporating all Stark exceptions
Takeaways: Stark & AKS/CMP RFIs

- RFIs outside of formal rulemaking process; CMS/OIG do not have to act on comments
  - Don't expect changes anytime soon
  - However, step in right direction
- Stark & AKS address fee-for-service fraud and abuse issues
  - Laws are real & perceived barriers to incentivizing value-based care models
- Significant costs to compliance
- Fraud and abuse waivers are a good start, need to expand
New CAH Survey Protocols

• New minimum qualifications for surveyors
  – CAH surveyor training courses and any associated prerequisites
• Surveyors will not provide CAH with list of all patients, staff or visitors interviewed or records reviewed
• CAH may ask that its staff accompany surveyors on-site
  – CAH staff must not interfere or delay survey
  – Staff must not interject during surveyor interviews
  – Surveyors reserve the right to exclude staff from confidential interview with patient or family member
  – Surveyors will not delay activities to await staff
  – CAH staff may not attend surveyor team meetings
New CAH Survey Protocols

• Copying and Printing
  – Surveyor access to copying machines – perform personally or watch CAH staff do so
  – Surveyors will make copies for CAH of all copies made, upon CAH request
  – Access to printer for EHR and electronic policies and procedures
    • Discouraged from printing entire medical record; only what is required for survey purposes
New CAH Survey Protocols

• Access to EHR
  – Surveyors may request passcode to allow EHR access
    • CAH should provide access in "read-only" mode to avoid inadvertent changes
    • CAH must ensure back up of data and security measures are in place

• CAH Staff Support of Surveyors
  – Surveyors may request access to nurses to review EHR with them
  – Surveyors may request experienced CAH EHR users to be assigned as "navigators"
    • Navigator must have access to EHR, policies, minutes and system audit features that identify date, time and author of entries or changes to the record
  – If some records are kept on paper, CAH staff must steer surveyors to the EHR or paper records as needed
New CAH Survey Protocols

- Goal of Surveyor EHR Review:
  - Determine whether staff can enter into and retrieve information necessary for patient's care in a timely fashion.
  - Determine staff competence in using EHR, as opposed to surveyor's ability to navigate system.

- Investigate what happens when EHR system is unavailable or offline. How to:
  - Register, admit, transfer, move or discharge
  - Order, determine and record medications and administration of meds
  - Order or determine diets
  - Order, determine and record treatments
  - Obtain lab reports and other test results
New CAH Survey Protocols

• Exit Interview/Explanation of acceptable Plan of Correction (POC)
  – Separately address each citation
  – Use a QAPI methodology to prevent recurrence of the deficient practice
  – Procedure for each CA taken
  – Procedure for monitoring CA for each citation (identifying position of person who will monitor and how frequently)
  – Dates of completion for each citation
Good FCA News?
The "Brand" Memo

• Prohibits DOJ from converting agency guidance into binding legal obligations
  – Cannot create binding requirements that do not already exist by statute or regulation
  – May not use noncompliance with documents as basis for proving violations of applicable law
  – Failure to comply with guidance does not mean the party violated the underlying legal requirements
Good FCA News?
The "Brand" Memo

• Medicare is largest payer of HC services
• CMS and MACs have a HUGE body of sub-regulatory guidance (does not go through the formal rule-making process)
• Different standards applied by different MACs
• Example: Local Coverage Determinations (LCDs)
  – DOJ frequently relies on these
  – Could providers argue LCDs are "guidance documents" and DOJ should not exclusively rely upon them???
Good FCA News?  The "Brand" Memo

• DOJ may continue to rely on agency documents for "proper" purposes (i.e., to explain or paraphrase existing statutes and regulations)

• DOJ may use as evidence that a party read such a document to help prove that the party had the requisite knowledge of the underlying statute or regulation
Good FCA News?
The "Granston" Memo

• Under FCA, when a private individual (whistleblower) files suit, gov't can intervene (or decline)

• FCA allows gov't to dismiss the action *notwithstanding* the objections of the *qui tam* relator
  – Sparingly used; cases traditionally proceeded
  – Providers spend considerable resources defending claim

• Potential shift in how DOJ treats meritless FCA cases
Good FCA News?
The "Granston" Memo

• 7 Factors DOJ may consider
  – Curbing meritless/frivolous claims
  – Preventing duplicative actions
  – Preventing interference with agency policies
  – Controlling litigation brought on behalf of U.S.
  – Safeguarding classified information/national security interests
  – Preserving government resources
  – Addressing egregious procedural errors
DOJ Relaxes Yates Memo

• Yates Memo required organizations to produce all relevant information on individuals involved in misconduct in order to receive any cooperation credit
• New policy: identify all individuals substantially involved in or responsible for the misconduct at issue
• DOJ expects these changes will increase organizations' willingness to cooperate and will lead to more efficient prosecution efforts
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
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
IA Legislative Update

• SF2290: County or city hospital bylaws may describe process for removal of trustee
• SF360: Changes to Newborn Safe Haven Act
• HF2305: Same coverage by health insurers for covered services if delivered via telehealth
• SF359: "Fetal heartbeat" abortion bill
  – Blocked by Judge on June 1
• HF2356: Direct primary care agreements are not considered insurance
Updated NPDB Guidebook

• Issued without prior notice or opportunity for input

• Guidance on interpretation of "investigation"
  – Agreement not to exercise privileges
  – Leave of absence
  – Reappointment review
  – Quality improvement plans
  – Requirement to operate with a qualified first assistant
Updated NPDB Guidebook

• Other notable items:
  – "Length of Restriction" section
  – Reporting a court-ordered change to a prior report
  – Private agreements between state agencies and providers
  – Impaired practitioners
  – Malpractice payment from sole shareholder P.C.
Posting Standard Charges

- Affordable Care Act (ACA § 2718; codified at 42 USC § 300gg-18)
- Rough outline (statutory language):
  - Applies to "[e]ach hospital operating within the U.S."
  - Must make public a list of hospital's "standard charges" in accordance with guidelines established by Secretary of DHS
  - Applies to "items and services" provided by the hospital
- 2015 Guidance: Either make available to the public (1) list of standard charges, or (2) policies permitting access to standard charges
Posting Standard Charges

• New requirements:
  – Effective January 1, 2019
  – "Standard charges" is undefined
    • Hospital's choice of how it will interpret
    • Does not mean chargemaster
  – Available on the internet in "machine readable" format (XML, CSV)
    • Does not include PDFs
    • Applies to all items and services

• Additional questions? CMS published helpful FAQs
  • Google: CMS standard charges FAQ; should be the first link
Telemedicine Update

• Bipartisan Budget Act of 2018 (BBA)
• Dialysis/ESRD-related services
  – Includes dialysis facilities and homes as telehealth originating sites
  – Only for the purposes of the monthly ESRD-related clinical assessments
  – No originating site facility fee is paid if the patient's home is the originating site
Telemedicine (BBA)

• Acute Stroke-Related Services
  – Telehealth services for the "diagnosis, evaluation, or treatment of acute stroke"
  – Removes restrictions on geographic locations and types of originating sites
  – Can be furnished in any hospital, CAH, mobile stroke unit, or any other site determined appropriate by the Secretary
CY 2019 Physician Fee Schedule
Pre-Recorded Information

• HCPCS Code G2010
  – Remote evaluation of recorded video and/or images submitted by the patient (e.g., store and forward), including interpretation with verbal follow-up with the patient within 24 business hours, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment
  – "Verbal follow-up" could take place via phone call, a/v communication, secure text, e-mail, or patient portal
HCPCS Code G2012

- Brief communication technology-based service by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion
- Requires direct interaction between the patient and the billing practitioner
CY 2019 Physician Fee Schedule
Peer-to-Peer Internet Consult

• CPT Codes 99451, 99452, 99446, 99447, 99448, 99449
  – Assessment and management services conducted through telephone, internet, or electronic health record consultations furnished when a patient’s treating physician or other qualified healthcare professional requests the opinion and/or treatment advice of a consulting physician or qualified healthcare professional with specific specialty expertise to assist with the diagnosis and/or management of the patient’s problem without the need for the patient’s face-to-face contact with the consulting physician or qualified healthcare professional
HIPAA Enforcement
Hot Off the Press!
(no pun intended)

• Patient contacted TV station to talk about dispute between patient and doctor
• TV reporter contacted doctor for comment
• (You guessed it) Doctor had a discussion with the reporter
• OCR investigation: inappropriate disclosure
  – Also, no disciplinary action taken
Allergy Associates of Hartford Settlement

• OCR:
  – "Doctor's discussion with the reporter demonstrated a reckless disregard for the patient's privacy rights and that the disclosure occurred after the doctor was instruction by the Privacy Officer to either not respond to the media or respond with "no comment"
  – "When a patient complains about a medical practice, a doctor cannot respond by disclosing private information to the media"

• $125,000 settlement
MD Anderson (CMPs)

• Three separate breaches reported to OCR in 2012 and 2013
• Theft of unencrypted laptop and loss of two unencrypted USB thumb drives all containing ePHI
• 34,883 affected individuals
Civil Monetary Penalties

• MD Anderson Cancer Center ($4.3M)
  – 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
In Other Television News...

- 3 Boston-area hospitals invited film crews on premises to film ABC documentary
- Did not obtain patient authorizations
- Did they not remember the 2016 OCR settlement with a NY-Presbyterian (filming of "NY Med")???
- You can guess what happened
Save My Life: Boston Trauma

- OCR investigation and settlement
  - Boston Medical Center ($100,000)
  - Brigham and Women's Hospital ($384,000)
  - Massachusetts General Hospital ($515,000)
BMC To Be Featured In New Medical Documentary

in News
October 10th, 2014

Boston Medical Center is proud to take part in a new medical documentary created by ABC. This mini-series focuses on BMC and two other Boston-area hospitals as they care for patients with traumatic injuries or medical emergencies like stroke or heart attack. Tentatively called “The Golden Hour,” the documentary-style television series will highlight the exceptional care that critically ill patients receive upon entering our Emergency Department and throughout their hospital stay. The team from ABC is expected to film at BMC for 10-12 weeks, starting the week of Oct. 6, and the series is slated to air in early 2015. You can read more about it in this article from the Boston Globe. BMC staff can have frequently asked questions answered here on BMC’s internal website.

Tagged education, trauma

Comments are closed.
ABC News shooting documentary series in local hospitals
Patient impact a worry with TV crews in Boston ERs

Filming of series in Boston hospitals stirs debate on balancing privacy concerns, public benefit

Over four months, ABC News cameras had unparalleled access to three of Boston's renowned hospitals — Mass. General Hospital, Brigham and Women's Hospital, and Children's Hospital.
The story continues...

The dean of one of America’s top medical schools was stunned.

Jeffrey Flier, who presides over Harvard Medical School, had just finished reading a story about the televised death of a man in a New York emergency room, a death aired without the family’s permission.

“How could this be allowed to happen?” the incredulous dean recently tweeted from @jflier.

Four minutes later came a reply tweet from Dr. Gerard Doherty, chief of surgery at Boston Medical Center. “The same group is filming a trauma series at your place (MGH) and ours (BMC) right now. On balance — good public education.”
Remember the Anthem Breach?

- December 2014-January 2015 phishing cyber attack
- Attackers stole ePHI of 79 million individuals
- This could happen to any of us, right?
Anthem, Inc. Settlement

• $16,000,000 settlement (largest in OCR history)
• Investigation revealed:
  – Failure to conduct an enterprise-wide risk analysis
  – Insufficient procedures to review system activity
  – Failed to identify and respond to known security incidents
  – Failed to implement adequate minimum access controls
No BAA with a Billing Service Provider?

• Advanced Care Hospitalists engaged billing services vendor
• Local hospital notified ACH that PHI was available on billing vendor's website
• Approximately 9,000 impacted individuals
Advanced Care Hospitalists Settlement

- $500,000 settlement
- OCR investigation revealed:
  - No BAA with billing services vendor
  - Failed to adopt a Business Associates policy until 2014 (ACH had been in operation since 2005)
  - Did not conduct a risk analysis until 2014
  - Did not adopt policies, procedures, or other security measures until 2014
Don't Forget to Terminate Former Employees' Access!

- Pagosa Springs Medical Center continued to allow a former employee to have access to PSMC's web-based scheduling calendar
- Investigation also revealed no BAA with online calendar vendor
- Impermissible disclosure (557 impacted individuals)
- $111,400 settlement
HIPAA - Any Relief in Sight?

• December 12, 2018 OCR issued a Request for Information (RFI)
• How can HIPAA be modified to promote coordinated, value-based care?
  – Encouraging information-sharing for treatment and care coordination
  – Facilitating parental involvement in care
  – Addressing the opioid crisis and serious mental illness
  – Accounting for disclosures of PHI for treatment, payment, HCO
  – Efforts to obtain acknowledgement of Notice of Privacy Practices
• Comments due February 11, 2019
Questions?

Michael W. Chase
mchase@bairdholm.com
(402) 636-8326

Abigail T. Mohs
amohs@bairdholm.com
(402) 636-8296