

# Top Health Law FAQs for Hospitals and Clinics

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# Kickbacks Post eClinical Works

- Government criticized referral program.
- Up to \$500 per “referral”.
- “Resulted in between 2.2 and 4.6 percent of new customers.”
- Are these really referrals?

# Should I Do Self-Audits During An Outside Audit?

- Nice to be ready to go, but ...
- Consultants routinely disagree.
- What will you do with charts that fail?  
(60-Day Rule)

# When Do The 60 Days Start To Run?

- After “identification.” This includes quantification.
- You need to make reasonable efforts to quantify in a timely manner. Presumption that you should accomplish that in 6 months.

# Can I Gainshare?

- Labels do not matter, but...
- Law DOES matter.
- Federal law prohibits payments intended to reduce services to Medicare beneficiaries.
- The government used to say gainsharing was illegal. That is totally last century.
- It is 100% clear that gainsharing/shared savings can be done legally.

# Gainsharing/Shared Savings/Co-Management/Your Label Here!

- At least 16 favorable OIG Advisory Opinions, starting in 2001.
- “Pending further notice from the OIG, gainsharing arrangements are not an enforcement priority for OIG unless the arrangement lacks sufficient patient in-program safeguards.” 79 F.R. 59715, 59729 (Oct. 3, 2014).
- The advisory opinions offer guideposts:
  - Payment caps.
  - Utilization targets.
  - Disclosure.
  - Hourly payments are low risk.

# Can You Have Long Term Gainsharing Payments?

- The conventional wisdom limits payments to one year.
- But see Advisory Opinion 12-22. “The management agreement is written with a three-year term, and thus is limited in duration.”
- Some people claim it only addresses co-management. They’re wrong.
- The payment must be reasonable.

# Can We Give Special Deals To Patients With High Deductibles?

- Understand how implied contracts work.
- Different prices are legal.
- How is a high deductible plan different from auto?
- Pricing is largely about intellectual consistency.

# Can I Accept Outside Referrals On My Scanner?

- Generally, yes but:
  - Any financial relationships must meet Stark exception.
  - Beware of state law, especially in Florida.
- The IDTF myth.

# An Internal Review Found Missing Documentation. Must We Refund?

- What type of service was it?
- Who was the payor?
- “If it isn’t written it wasn’t done” is pithy, but not law.
- If you refund, who should it go to?

# When A Device Company Replaces A Defective Device, Are There Special Rules?

- Yes! The DRG is reduced for certain replacement devices if the hospital gets the device for free/discount  $\geq 50\%$  of the cost of the device, and when the assigned MS-DRG is noted in the IPPS rule. MCPM Ch. 3 § 100.8.
- Must use condition code 49 or 50, along with value code FD.

# Reminder About Charging For Recalled Devices

*As a reminder, section 2202.4 of the Provider Reimbursement Manual, Part I states, "charges should be related consistently to the cost of the services and uniformly applied to all patients whether inpatient or outpatient." Accordingly, hospital charges with respect to medical devices must be reasonably related to the cost of the medical device. If a hospital receives a credit for a replacement medical device, the charges to Medicare should also be appropriately reduced.*

MCPM Ch. 3 § 100.8.

# Free Transportation

- Federal antikickback and CMP, state law analogs.
- Several OIG advisory opinions.
- January 2017: new safe harbor to antikickback and exception to the beneficiary inducement prohibition.
- Protects free or reduced transportation by an “eligible entity” if . . .

# Free Transportation

1. There is a policy that is applied uniformly and consistently and does not take into account the volume or value of referrals;
2. No air, luxury, or ambulance-level transportation;

# Free Transportation

3. No marketing of the program or advertising during the ride, driver not paid on per-beneficiary basis;
4. Available only to “established” patients;
5. Available only within 25 miles of the provider/supplier (50 miles, if rural);

# Free Transportation

6. Available only for the purpose of obtaining medically necessary items and services (transportation back to a patient's home is protected);
7. Provider/supplier bears the cost of the free transportation;

# Free Transportation

- Local shuttle services on a set schedule and route are okay if they:
  - Comply with all other safe harbor requirements EXCEPT no policy is required and services need NOT be limited to established patients for medically necessary items and services (e.g., employees and/or family may use).
- “Local” = < 25 mi between stops (< 50 mi in rural areas).

# Ransomware And HIPAA

- WannaCry in May, Petya in June.
- Refresher on the guidance from OCR on July 11, 2016:

<http://www.hhs.gov/sites/default/files/RansomwareFactSheet.pdf>

# Avoid, Mitigate Ransomware Attacks AND Comply With HIPAA

- Security risk analysis: Specifically include ransomware as a line item.
- Contingency plan:
  - Backup frequently (consider offline and unavailable from networks); and
  - Test backup recovery process.
- Treat ransomware as you would a “security incident” and follow your HIPAA security incident response plan and procedures immediately upon detection.
- Train workforce on early signs of ransomware.

# Do You Have To Report A Ransomware Attack?

- Is the PHI unsecured?
  - OCR says a ransomware attack of an encrypted computer that is not powered down could be a breach of unsecured PHI.
- Is there a low probability the information has been compromised?
  - Now, two additional factors to consider:
    - 1) High risk of unavailability of data?
    - 2) High risk to the integrity of the data?
    - “In those cases, entities must provide notification to individuals without unreasonable delay, particularly given that any delay may impact healthcare service and patient safety.”

# OMHA Backlog

- Federal court order on 12/05/2016:
  - 30% reduction from the current backlog of cases pending at the ALJ level by 12/31/2017;
  - 60% reduction by 12/31/2018;
  - 90% reduction by 12/31/2019; and
  - 100% reduction by 12/31/2020.

# OMHA Backlog

- Final rule effective January 2017:
  - Some Medicare Appeal Council decisions are precedential.
  - Now there are attorney adjudicators.
  - Statistical sampling appeal date based on last case in the bunch.

# OMHA Backlog

- FY 2018 proposed budget requests \$242 million for OMHA (nearly 2x the budget of FY 2017) and a legislative package to address the backlog.
- Currently, it takes 1,000 days for OMHA to adjudicate a non-beneficiary appeal.

# Can We Release Medical Records We Received From A Third Party?

- Under HIPAA, “PHI” is any health information, created, received, or maintained by a covered entity.
- HIPAA lets a covered entity disclose PHI in a designated record set.
- Alcohol and drug abuse records protected by federal law should NOT be redisclosed.
- Remember state law considerations.

# Do Medicare Rules Apply To MA Patients?

- No regulation expressly suggests this.
- Each program points a finger at the other.
- Review your payer agreement and provider manual.
- Stark may be a different story.

# Networked Medical Devices – What Are The Risks?

- Growing emphasis on medical device cybersecurity in recent years.
  - Increasing number of medical devices connect to internet and provider networks.
- FDA has issued warnings and guidance.
- OIG Work Plan past two years identified networked medical devices as a focus.

# Networked Medical Devices – What Are The Risks?

- Risks to patient safety
  - Devices like pacemakers and insulin pumps can be compromised by hackers or viruses, affecting device operation.
- Regulatory risks
  - HIPAA privacy and security concerns.
  - Unauthorized access to PHI.
- What does this mean for providers?

# Networked Medical Devices – What Are The Risks?

- Know your vulnerabilities and be prepared for a breach.
  - Existing/legacy devices – focus on updates, firewalls, and patches.
  - New devices – focus on procurement and vendor/supplier diligence.
- Track and dispose of devices.

# Networked Medical Devices – What Are The Risks?

- Know where data is transmitted/stored and who has access (e.g., subcontractors).
  - Is data transferred outside the U.S.?
- Have appropriate agreements in place (e.g., BAAs, ISAs, etc.).
  - Understand rights re audits, updates, notifications.
- Risk assessments and incident response plans are important as ever.

# Semiannual OIG Report

- Summarizes OIG's work October 1, 2016 to March 31, 2017.
- Report highlights the following focuses:
  - Payments after a beneficiary's death.
  - Express lane eligibility.
  - Payments for incarcerated beneficiaries.
  - Improper payments for chiropractic services and cochlear devices.

# Semiannual OIG Report

- Other noted OIG efforts:
  - Prescription drug rebates from pharmaceutical manufacturers.
  - State verification of nursing homes correcting deficiencies identified during state surveys.
  - CMS's management of the Quality Payment Program.

# Can I Charge Patients For Completing Forms?

- Potentially, but there are risks and issues you need to consider.
- Must make sure it is not part of a covered service.
- Review your payor contracts.
- Check state law and board policies.

# Can I Charge Patients For Completing Forms?

- Be aware of local customs and ethical guidelines.
- Rules might differ depending on the type of form requested.
  - Under federal law, employees are responsible for cost of completion of FMLA forms.
- In any event, patients should be clearly notified in advance.

# HIPAA Audits

- Currently in Phase II of audit program: Desk Audits
- Toolbox of ensuring compliance—not done in pursuit of CMP.
- OCR thinks of this as a “free consultation” with feedback in the draft report.
  - You *\*can\** move from audit to compliance review if you:
    - Don’t respond; or
    - Send documents that make it look like you have no idea what you’re doing.
- OCR not sure if on-site audits will be coming before end of 2017.

# HIPAA Audits

- Is your notice “prominent” enough on your website?
  - *“An example of prominent posting of the notice would include a direct link from homepage with a clear description that the link is to the HIPAA Notice of Privacy Practices.”*
  - Down at the bottom of the page is not good enough.
- Do you have contact information for business associates?

# Access To PHI/Fees For Records

- New FAQs and a “clarification.”
- Generally, individuals have a right to access their own PHI.
- OCR “clarified” that individuals may direct a third party to have access without signing an authorization.

# Fees For PHI

- “Reasonable, cost-based fee.”
- ONLY labor, supplies, and postage:
  - No retrieval fees, no fees for time spent searching for records;
  - Labor is only for creating and delivering;
  - May charge for supplies (e.g., paper, USB drive, etc);
  - Can’t require someone to purchase USB; information can be mailed or emailed.

# Fees For PHI

- Careful applying any fees authorized under state law.
- “Covered entities should provide ...access ... free of charge.”
  - HIPAA does allow you to charge.
- Can charge for a summary of the info if the person agrees in advance to both the summary and the fee.

# Fees For PHI: Is \$6.50 The New Maximum?

- Three methods:
  - Actual costs
  - Average cost
    - Schedule of costs for labor based on average labor cost
    - Can charge per page only where PHI is in paper form and person asks for a paper copy
  - Flat fee of \$6.50 maximum
- Notify individuals in advance of the approximate fee for copies.

# Fees For PHI

- Fee limits apply to individuals own requests and requests to give PHI to a third party.
- Requests by third parties based on patient's authorization are not subject to these fees (unless the third party is forwarding the patient's request).

# What Kind of Procedures are Required or Permitted?

- Can require written requests.
- Cannot create a barrier to, or unreasonably delay, access.
  - e.g., cannot require individual to request in person or via mail.
  - e.g., cannot require full HIPAA authorization.
- Covered entity must verify identity.

# Sending Records Via Unsecure Email

- Individual has a right to specify the mode of transmission or transfer.
- Give a “light warning” about the security risks.
- Covered entity is not responsible for a disclosure of PHI while in transmission to the individual based on the individual’s access request to receive the PHI in an unsecure manner.

# MOON

- MOON = Medicare Outpatient Observation Notice
  - Standardized notice to inform Medicare beneficiaries that they are outpatients receiving observation services and are not inpatients of a hospital.
  - Must be provided no later than 36 hours after the observation services are initiated (or sooner if individual is transferred, discharged, or admitted as an inpatient).
  - Must be signed by the patient or the patient's representative (or document the refusal to sign).
  - Must be accompanied by a verbal explanation.
- Enforcement Date: 3/8/2017

# When Do I Deliver The MOON?

- Check state law
- Can you provide it in the first 24 hours?
  - Yes, but don't provide it too early (i.e., at the initiation of the observation services)
  - CMS wants the notice delivered only after they have spent some time in observation status
  - “[P]atients may be completely preoccupied with concern for their safety and well-being, as they may be unsure of their diagnosis at a time when the signs and symptoms of their presenting condition(s) may be at the height of their clinical acuity. At the initiation of outpatient observation services, patients also may be overwhelmed and confused by notices and hospital paperwork that are presented at the time, often simultaneously.” 81 Fed. Reg. 57043 (Aug. 22, 2016).

# Elder Justice Act

- Imposes obligations on LTC facility owners/operators to provide **annual notice** of elder abuse, neglect, and exploitation reporting obligations to “covered individuals” (e.g., employees, agents, and contractors)
- Each covered individual is required to meet the reporting obligations of the Elder Justice Act
- May appear in contracts for parties providing services to LTC facilities
  - Any employee or contractor providing services under the agreement should be aware of the reporting obligations

# What's Happening With Section 1557?

- *Franciscan Alliance, Inc. et al v. Burwell*
  - Injunction applies to “gender identity” and “termination of pregnancy”
  - DOJ: motion for voluntary remand and stay
  - OCR: public statement to continue enforcement of other important provisions
- Use of the private right of action is on the rise

# Reminder: QPP Reporting



2017

## Performance:

The first performance period opens January 1, 2017 and closes December 31, 2017. During 2017, record quality data and how you used technology to support your practice. If an Advanced APM fits your practice, then you can join and provide care during the year through that model.

March 31, 2018

## Send in performance data:

To potentially earn a positive payment adjustment under MIPS, send in data about the care you provided and how your practice used technology in 2017 to MIPS by the deadline, March 31, 2018. In order to earn the 5% incentive payment by significantly participating in an Advanced APM, just send quality data through your Advanced APM.

2018

## Feedback:

Medicare gives you feedback about your performance after you send your data.

January 1, 2019

## Payment:

You may earn a positive MIPS payment adjustment for 2019 if you submit 2017 data by March 31, 2018. If you participate in an Advanced APM in 2017, then you may earn a 5% incentive payment in 2019.

# All Charts Must Be Signed, Right?

The rules will vary based on the payor, but Medicare doesn't require a signature.

**“11. Is the physician's signature required on each page of the documentation?”**

No. The guidelines only state that the identity of the observer be legibly recorded.”

# Program Integrity Manual, CMS Pub 100-08 § 3.3.2.4, *Signature Requirements*

- *If the signature is missing from an order, MACs and CERT shall disregard the order during the review of the claim (e.g., the reviewer will proceed as if the order was not received).*
- *If the signature is missing from any other medical documentation (other than an order), MACs and CERT shall accept a signature attestation from the author of the medical record entry.*

# Presenters



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