

# Health Law Grab Bag: FAQs for Hospitals and Clinics

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# Can I Disclose PHI to a Potential Buyer in a Deal?

- Yes, under HIPAA . . .
- But check state law, too.
- What about a private equity buyer?
- Do I need a BAA?

# I'm Closing a Clinic. What Do I Need to Do?

- Tell your patients and help them find a new provider.
- Make arrangements for maintaining patient records.
- Notify boards and licensing agencies (may vary by state).
- Notify employees.
- Wind down the business.

# Dos, Don'ts and Maybes of Delegating to a Support Organization.

- Do:
  - Outsource administrative functions.
  - Document the arrangement in writing.
  - Regularly review the services provided by, and compensation paid to, the support organization.
  - Retain authority over hiring, promoting and disciplining licensed/certified individuals.
  - Review communications from the support organization to practice staff.
  - Review state law.

# Dos, Don'ts and Maybes of Delegating to a Support Organization.

- Don't:
  - Delegate clinical decision making authority.
  - Allow the support organization to decide compensation for licensed/certified providers.
  - Accept financial assistance from a support organization that won't be repaid.
  - Let the support organization determine whether to prioritize high-profit procedures or payors.

# Dos, Don'ts and Maybes of Delegating to a Support Organization.

- Maybe:
  - Transfer ownership of medical equipment to the support organization.
  - Lease office space from the support organization.
  - Use the support organization's trade name in marketing.
  - Call a healthcare lawyer with questions.

# I Heard About a Big Decision in the AseraCare case. What Happened?

- FCA claim against hospice provider based on certifications that patients were terminally ill.
- Jury verdict in favor of the government set aside by the trial court.
- Court of appeals held that the government must show the underlying clinical judgment reflects an “objective falsehood” which requires more than a competing opinion from the government’s expert.
- Case remanded to trial court.

# Can I Share the Legal Advice I Get With Others?

- Yes, but it risks waiving the attorney-client privilege.
- Beware of the email forward.
- May be able to use “common interest” privilege but its validity is far from clear.
- Share at your own risk.
- Copying the lawyer will not guarantee privilege.

# Can I Give Gifts to Patients?

- Generally not if the patient is a Medicare or Medicaid beneficiary.
  - Unless the gift has a retail value of no more than \$15.00 per item and \$75.00 in the aggregate per patient annually.
  - The item may not be cash or a cash equivalent.
- Additional limited exceptions, including for preventative care in certain circumstances and co-pay or deductible waivers based on financial need.
- State law may be more restrictive.

# Should My Organization Have a Compliance Program?

- Yes, it is required if you want to qualify as an MA organization.
  - It's a good idea regardless.
- OIG has provided guidance regarding voluntary plans for various entity types at: <https://oig.hhs.gov/compliance/compliance-guidance/index.asp>
- Not a replacement for HIPAA compliance or a security risk assessment.

# Video Cameras in Hospitals

- Patient awareness of monitoring
- Patient consent to recording
- HIPAA-compliant authorization to disclose

# Declining Medicare Patients

- Can a Medicare enrolled physician decline to provide a particular service to a Medicare recipient because the reimbursement is too low? What about because they just don't want to do it?

# Declining Medicaid Patients

- Can a Medicaid enrolled physician decline to provide a particular service to a Medicaid recipient because the reimbursement is too low? What about because they just don't want to do it?

# Can I Bill Incident To in the Hospital?

- No, “incident to” is office only.
- Do not confuse office “incident to” to outpatient therapeutic services “incidental to the services of a physician.”

# The Physician Payment Sunshine Act

Applicable manufacturers and GPOs  
must report:

- certain payments or other transfers of value provided to physicians and teaching hospitals, and
- any ownership or investment interest that physicians or their immediate family members have in the applicable manufacturer or GPO.

# Can I Adjust My Fees to Out-of-Network Patients to Mirror the Network?

- How the insurer reimburses out-of-network services may affect the analysis.
  - Fee schedule.
  - Percentage of charges.
  - Percentage of fee schedule.

# Can We Give Prompt Pay Discounts?

- What rationale supports the discount?
  - Insurance contracts prohibit “a billing fee.”
  - Is it interest?
- I love my dentist.

# Can We Offer 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;
3. No marketing of the program or advertising during the ride, driver not paid on per-beneficiary basis;

# Free Transportation

4. Available only to “established” patients;
5. Available only within 25 miles of the provider/supplier (50 miles, if rural);
6. Available only for the purpose of obtaining medically necessary items and services (transportation back to a patient’s home is protected); and
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).

# Free Transportation

- Should be from site-to-site (and not to third party referral sites).
- Financial means testing helps.
- Do not condition on high dollar treatments, insurance coverage, or diagnosis.
- Free transportation outside the primary service area is risky.

# Record text messages with patients?

- No legal requirement.
- Treatment considerations.
- Malpractice lawsuit considerations.
- Should phone call content be documented?

# Signage for “public awareness”

- If a clinic enrolls a practice location at a non-traditional setting, such as a high school, and leases the space as non provider-based to perform a service, is the clinic required to have signage (public awareness) at the leased space? Is informing the patient at time of scheduling where to go for the visit enough?

# Signage for “public awareness”

- The public awareness signage is a Medicare requirement for provider-based departments of hospitals.
- Underlying policy is about awareness of co-insurance liability.

# What is the status of the provider-based guidance on co-location?

- May 2019 draft guidance.
- Comments due July 2019.
- No other news. (Final 2020 OPPS rule due in November.)

# “What exactly is an IDTF?”

- A Medicare creature: Independent Diagnostic Testing Facility.
- 42 C.F.R. 410.33(a): “An IDTF may be a fixed location, a mobile entity, or an individual nonphysician practitioner. It is independent of a physician’s office or hospital; however, these rules apply when an IDTF furnishes diagnostic procedures in a physician’s office.”

# “What exactly is an IDTF?”

- Is the terminology IDTF just a Medicare term (like “incident to”)?
- Is an IDTF a “physical place” where patients go for testing?
- If so, how is the TC of the test billed (what POS is reported?)
- Must the IDTF employ the interpreting physician?

# Extra rules for IDTFs

- May not share a practice location.
- Each location (and mobile unit) must enroll separately.
- Supervising physician – must demonstrate proficiency in tests; limited to 3 sites; may not order tests.
- Written orders required (i.e., no phone orders).
- May not directly solicit patients.

# Debunking myths

- There is still confusion about whether physicians must become an IDTF if they bill for scans ordered by outsiders.
  - The manual guidance indicating there is a limit on outside scans is gone.
- In the vast majority of situations, even the old manual language didn't require physician groups to enroll as an IDTF to perform outside scans.

# Medicare Benefit Policy Manual, Chapter 1, Section 10.2

- **d. Commencement of inpatient status** - *Inpatient status begins at the time of formal admission by the hospital pursuant to the order, including an initial order (under (B)(2)(a)) or a verbal order (under (B)(2)(b)) that is authenticated (countersigned) timely, by authorized individuals, as required in this section. If the practitioner responsible for authenticating (countersigning) an initial order or verbal order does not agree that inpatient admission was appropriate or valid (including an unauthorized verbal order), he or she should not authenticate (countersign) the order and the beneficiary is not considered to be an inpatient. The hospital stay may be billed to Part B as a hospital outpatient encounter.*

# Inpatient admissions

- 42 C.F.R. 412.3(d)(1)

Except as specified in paragraphs (d)(2) and (3) of this section, an inpatient admission is generally appropriate for payment under Medicare Part A **when the admitting physician expects the patient to require hospital care that crosses two midnights.**

# The State of E&M

- Altered and/or delayed until 2021 in the 2019 PFS Final Rule
- 2020 PFS proposes additional revisions to E/M documentation and payment policies
- No blended rates
- More to come in December webinar

# 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?

# Conscience

## Objections/Section 1557

- “Protecting Statutory Conscience Rights in Health Care”
  - Originally effective July 22, 2019.
  - Implementation of the regulations delayed through at least November 22, 2019.
- Commenters expressed concern over conflicts with Section 1557 and other anti-discrimination statutes.

# Can We Send Emails to Patients?

- Yes – there is no law preventing it.
- Must take precautions.
- Unencrypted email?
  - If a patient asks for a copy of his/her PHI, can send in an unencrypted email IF the patient consents to it after hearing about the risk. Document the conversation.
  - Advice: encrypt email to patients; check the address three times before sending.

# Subpoenas for Medical Records

- Evaluate whether service is proper.
- Is there an authorization enclosed? Is there an authorization on file?
- Determine whether HIPAA's requirements are met.
- Determine whether state law is more restrictive.

# Do I Need to Do a Security Risk Analysis?

- YES!!!
- An accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of ePHI held by the Covered Entity.
- Risk Analysis vs. Gap Analysis.
- Ransomware, encryption, software patches.
- Recent CMP: The University of Texas MD Anderson Cancer Center (\$4.3M).

# Can We Release Medical Records We Received from a Third Party?

- Yes!!! 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.

# Is \$6.50 the maximum charge for copies of PHI?

- 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.

# Recent OCR Settlements

- \$10,000 settlement against CE for social media disclosure (10/2/2019)
- \$100,000 settlement against BA for breach and failure to conduct risk assessment (5/23/2019)
- \$3,000,000 settlement for failure to properly investigate, perform risk assessments, timely notify, and execute BAAs (5/6/2019)

# \$85,000 Right of Access HIPAA Settlement

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HHS Office for Civil Rights in Action



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September 9, 2019

## OCR Settles First Case in HIPAA Right of Access Initiative

Today, the Office for Civil Rights (OCR) at the U.S. Department of Health and Human Services is announcing its first enforcement action and settlement in its Right of Access Initiative. Earlier this year, OCR announced this initiative promising to vigorously enforce the rights of patients to receive copies of their medical records promptly and without being overcharged.

Bayfront Health St. Petersburg (Bayfront) has paid \$85,000 to OCR and has adopted a corrective action plan to settle a potential violation of the right of access provision of the Health Insurance Portability and Accountability Act (HIPAA) Rules after Bayfront failed to provide a mother timely access to records about her unborn child. Bayfront, based in St. Petersburg, Florida, is a Level II trauma and tertiary care center licensed as a 480-bed hospital with over 550 affiliated physicians.

OCR initiated its investigation based on a complaint from the mother. As a result, Bayfront directly provided the individual with the requested health information more than nine months after the initial request. The HIPAA Rules generally require covered health care providers to provide medical records within 30 days of the request and providers can only charge a reasonable cost-based fee. This right to patient records extends to parents who seek medical information about their minor children, and in this case, a mother who sought prenatal health records about her child.

In addition to the monetary settlement, Bayfront will undertake a corrective action plan that includes one year of monitoring by OCR. The resolution agreement and corrective action plan may be found at: <https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/agreements/bayfront/index.html>

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# HIPAA Compliant Vendors

- Careful: Purchasing “HIPAA compliant” products and services does not guarantee HIPAA compliance.
- Choose vendors wisely by reviewing:
  - HIPAA experience and knowledge
  - BAA terms
  - Risk Assessments and policies

# Contact Information



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