The Annual FAQ Session

Health Law Webinar

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Fredrikson

Where Law and Business Meet®

What is Going on with Non-competes?

- Complete bans with few exceptions:
  - *CA, MN, ND, and OK (NY likely).*
- Bans with salary threshold exceptions:
  - *CO, IL, ME, MD, NH, OR, RI, VI, and WA.*
- Bans with civil (and sometimes criminal) penalties:
  - *CA, CO, IL, ME, NV, OR, VI, WA, WI, and D.C.*
- Federal Trade Commission's proposed regulation (expected Spring 2024).

What Tools Remain Without Non-Competes?

- Non-competes during employment.
- Non-competes in sale of business context.
- Non-solicitation restrictions:
  - *Customers, suppliers, patients, employees, etc.*
- Confidentiality provisions:
  - *Trade Secrets.*
  - *Patient Lists.*
- Duty of Loyalty.

When Must We Pay for Interpreter Services?

- Consider the four factors.
  - *Number*
  - *Frequency*
  - *Nature/Importance*
  - *Resources Available to Provider*
- If determined to be reasonable and necessary – provider pays.

What are the Limitations for Translation Services?

- Providers cannot force an individual to provide their own interpreter.
- Providers cannot force an adult accompanying a patient with limited English skills to interpret unless it is an emergency or patient specifically requests the adult facilitate communication.
- Providers are prohibited from forcing a minor child to facilitate the interpretation except, again, in emergency situations.
- Only qualified bilingual staff persons.

Can a Pharmaceutical Company or Other Distributor Offer a "Reward" System to Clinics or Other Health Care Entities?

- This is likely permissible.
- This is likely just a discount system, and price is not a kickback.
- Some flags:
  - *This does NOT apply to a similar clinic-patient reward system.*
  - *If discount/reward is done using a rebate system and reimbursement is cost based, it must be disclosed.*
  - *Cannot discriminate against a Federal health care program.*
  - *Remember eClinicalWorks.*

Can We Offer Free Transportation?

- Consider the anti-kickback statute and Civil Monetary Penalties. There is a safe harbor for transportation services. Some things to consider:
  - *"Fanciness" level*
  - *Established patient*
  - *primary service area*
  - *shuttle service*
  - *No advertising*
- Generally, more concerned with moving a patient to a facility rather than away from it.

Can We Charge Less Than Our Usual Fee for Self-Pay Patients and High Deductible Plans?

- Risky business.
- Can be viewed as insurance fraud.
- Could also impact provider's right to collect insurance from payor.
- If you do charge less, consider risk mitigation measures.

Do We Need to Bill Everyone the Same?

- Not really, but less clarity than we would like.
- Medicare will pay the lower of the fee schedule, actual charge, or the usual and customary charge (median charge).

Can We Charge a Patient Who Does Not Return Equipment?

- Legal Considerations
  - *Likely OK to charge, so long as confidentiality is in place.*
  - *Avoid the security deposit approach (no cost upfront).*
- Practical Considerations
  - *Credit card hold only works for three days.*

Where and When Must an Order be Documented Under Medicare?

- In many cases, it does not need to be documented at all.
- CMS has acknowledged this including explaining why it chose to impose documentation requirements in certain circumstances but not in general.
- Check the regulation. Start with 42 C.F.R. Part 424.
  - *Manuals and audits are often incorrect on documentation requirements*
- What about Medicaid and other third-party payors?

What Can a Physician Get Compensation Credit For?

- Under Stark there are two ways to obtain compensation:
  - *Profit Share: Must be done uniformly for the whole group or for subcomponents of the group of five or more doctors. This approach must include all DHS.*
  - *Productivity Bonus: Pay physicians for things they personally did, things that are incident to things they personally did, or things that are not DHS.*
    - Diagnostic tests cannot be incident to.

What Do I Need to Know About Hiring a Practice Management Company?

- There are many issues to consider.
- Scope of services that can be outsourced.
- How the fee should be calculated, such as a percentage of revenues, cost-plus, or a flat fee.
- Federal and state laws, as well as board rules, are all potentially relevant.

Should a Physician Who Refers to an ASC (But Does Not Perform Surgeries) Have a Direct Ownership Interest in It?

- Risky, if the referring physician receives distributions or any return on investment.
- Since the physician does not perform procedures at the ASC, he or she would not meet the 1/3 test in the applicable AKS safe harbor.
- AKS does not require meeting all elements of a safe harbor. But…
- Indirect ownership, such as through a group practice, could be an option.

Do Medicaid FFS or Medicaid MCO plans have to follow the Medicare Inpatient-Only List?

- Not a federal requirement of participation.
- Possibly required under state law or MCO agreements.

A Patient E-Mailed Me. Can I Respond By E-Mail?

- Government guidance says it's reasonable to assume (unless otherwise stated) that e-mail communications are acceptable to the patient.
- OK for the physician to first alert the patient of the potential risks of unencrypted communications.
- Phish food?

I’m Buying a Medical Practice. Do I need a BAA with the Seller?

- No.
- BAAs are used when a third party is performing a function on behalf of a covered entity.
- There is an exception for disclosure of PHI in connection with “health care operations” which includes the sale of a practice.

My Practice Sends Secure Texts to Patients. Do We Need to Preserve These Messages?

- Preservation is not “required” but…
- Consider content of the messages. May want to preserve texts if they contain information relating to treatment.
- Are you billing for it?
- Would saving the texts be helpful in a dispute with the patient?

Pixels, Cookies and Tracking: What is all This Health Care Website Litigation About?

- Dozens of class action lawsuits filed against health care entities in the past year.
  - *Some older, similar cases.*
    - $18.4 million settlement.
  - *Mostly hospital systems.*
- Central claim in the cases:
  - *Health care entities cannot share information with tech companies provided/gathered on the entities' websites.*
  - *Using tracking technologies does that.*

What's the Risk From Using These Technologies?

- Short answer: It's (probably) too early to tell.
- HHS's Office of Civil Rights issued **guidance**.
- Newer cases are not far along.
- Older cases:
  - *Often use somewhat different theories.*
  - *Mixed statuses.*

- OCR or FTC action?

What's Our Risk? Should We Take Tracking Technologies Off Our Website?

- Evaluate your exposure.
- What tools are you using?
  - *Third-party versus internal tools.*
- What are your website's capabilities?
- What part(s) of your website is it on?
- What is in your website's privacy policy?
- Videos?
- What benefit are you getting?

HIPAA Might Change: What's Happening?

- OCR is **proposing** changes to HIPAA's Privacy Rule.
- Purpose: To protect information related to reproductive health care.
  - *Meant to protect both patients and professionals.*
- The comment period ended June 16.

We Don’t Provide Reproductive Health Care. Are We Affected?

- As proposed, yes.
- Very broad definition of reproductive health care.
- “Potentially related.”
- OCR expects:
  - *Every NPP will need to be changed, and*
  - *35% of BAAs will require significant modification.*

HIPAA Might Change: What Do I Need To Do?

- Once finalized, covered entities likely will have 240 days to comply.
  - *If issued today: April 5, 2024.*
- So, right now, legally nothing yet.
- But we recommend planning and preparing.

Where Does a Supervisor Need to be Located for Incident To Services?

- Direct Supervision
  - *410.32(b)(3)(ii): "Direct supervision in the office setting means the physician must be **present in the office suite** and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed."*

Where Does a Supervisor Need to be Located for Incident To Services?

- Office Suite
  - *We are not proposing that there must be any **particular configuration of rooms** for an office to qualify as an office "suite." However, direct supervision means that a physician must be in the **office suite** and immediately available to provide assistance and direction. Thus, a group of **contiguous rooms** should in most cases satisfy this requirement. **We have been asked whether it would be possible for a physician to directly supervise a service furnished on a different floor. We think the answer would depend upon individual circumstances** that demonstrate that the physician is close at hand…*

Where Does a Supervisor Need to be Located for Incident To Services

…The question of physician proximity for physician referral purposes, as well as for incident to purposes, is a decision that only the local carrier could make based on the layout of each group of offices. For example, a carrier might decide that in certain circumstances it is appropriate for **one room of an office suite to be located on a different floor, such as when a physician practices on two floors of a townhouse**."

– *63 Fed Reg. 1685, Jan 9, 1998*

Do we Need to Enroll Each Site? A Physician's Home?

- In general, there is a regulation that says suppliers and providers need to enroll their location and report changes to practice location. However, there is no real definition for what is a practice location.
- Conflicting guidance some of which suggests the answer is yes, a home should be enrolled. However, guidance is JUST guidance.
- Our recommendation is that if there is another site to enroll - use that.

I Want to Buy a Health Care Business. Do I Need to Notify the State?

- There is a growing trend of states passing laws requiring government review or approval health care transactions.
- Nine states with laws on the books and legislation pending in two additional states.

What is the Corporate Transparency Act?

- New federal law that establishes new and substantial reporting requirements for new and existing entities.
- Goes into effect on January 1, 2024.
- Has significant penalties for non-compliance.
  - *Both civil and criminal penalties.*

Who is Required to Report?

- "Reporting Companies"
  - *Includes domestic and foreign entities.*
  - *If you need to file with the secretary of state, pay attention to this new law.*

What Should be Reported Under the Corporate Transparency Act?

- Information about Reporting Company
  - *Legal name, trade names, address, TIN, etc.*
- Information about Beneficial Owners
  - *Full name, current address, ID Number and ID, etc.*
- Information about Company Applicants
  - *Full name, current address, ID Number and ID, etc.*

What's New With the No Surprises Act?

- FAQ addressing maximum out-of-pocket (MOOP) limits:
  - *Cost sharing for services by a nonparticipating provider, facility, or provider of air ambulance services IS considered cost sharing for benefits provided outside of a plan's network for purposes of the MOOP limit.*
  - *Plan and issuers CANNOT treat a provider, facility, or provider of air ambulance services with which it has a contractual relationship as OON for purposes of the MOOP limit while also treating them as participating for purposes of the NSA.*

What's New With the No Surprises Act?

- Good Faith Estimate (GFE):
  - *Co-provider/facility provisions remain indefinitely delayed.*
  - *Still no guidance on process for patients using insurance (RFI issued September 16, 2022).*
  - *Facility fees are included in definition of "items and services" for purposes of TiC Final Rules and GFE.*

What's New With the No Surprises Act?

- Prohibition on Gag Clauses on Price and Quality Information in Provider Agreements:
  - *Attestation due December 27, 2023, but only plans and issuers must submit.*

What's Happening with PDRP and IDR?

- Effective August 3, 2023, processes temporary suspended.
- Why?
  - *Texas Medical Association, et al. v. United States Department of Health and Human Services*, Case No. 6:23-cv-59-JDK (TMA IV).
  - Vacated certain portions of 45 C.F.R. § 149.510, 26 C.F.R. § 54.9816-8T, and 29 C.F.R. § 2590-716-8 (parallel provisions governing the Federal IDR).
  - The Departments need to (again) comply with order.

Can we Do Split/Shared Visits in the Clinic?

- No…but yes. This is a semantics issue.
- 42 CFR § 415.140 says that split/shared visits happen in a “facility.” Clinics are not included in the definition for facility.
- When this happens in a clinic it is called incident to. Could call joint visit or co-visit but not split/shared visit.

I Have Never Evaluated a Patient In Person. May I Prescribe a Controlled Substance Through Telemedicine?

- Now: Probably yes.
- After November 11, 2023:
  - *As of now:*
    - If you established a “telemedicine relationship via COVID-19 telemedicine prescribing flexibilities”: Yes, through November 11, 2024.
    - If not: Generally no.
  - *This might change.*

What is a “Telemedicine Relationship via COVID-19 Telemedicine Prescribing Flexibilities”?

- 21 C.F.R. § 1307.41(b) and 42 C.F.R. § 12.1:

  1)Have not conducted an in-person medical evaluation and

  2)Prescribed the patient a controlled substance via telemedicine through November 11, 2023.

- Takeaway: If someone is your telemedicine patient on or before November 11, 2023, but you do not issue the patient a prescription between March 16, 2020 and November 11, 2023, you will need to conduct an in-person evaluation starting November 12, 2023.

Stay Tuned to Your Telemedicine

- This extension is temporary and will automatically expire.
- The DEA is working on new rules.

Can We Permit Medicare Patients To Use Our "Cash Only" Telehealth Services?

- We are asking about this one!
- Generally speaking, you cannot charge a Medicare patient for a covered service. Telehealth is a covered service.
- However, it seems unfair to say that only Medicare patients cannot access the cash only telehealth service.

Do Medicare Advantage Plans Need to Follow the Two-Midnight Rule?

- In April, CMS finalized rule changes related to Medicare Advantage and several other issues.
- Amended 42 C.F.R. § 422.101(b)(2): General coverage and benefit requirements.
- According to CMS, the change mainly just "**clarifies**" the rules to ensure people on MA get at least as good of benefits as those offered by traditional Medicare.

§ 422.101(b)(2): Criteria Clarification

- "General coverage and benefit conditions included in Traditional Medicare laws, unless superseded by laws applicable to MA plans. **This includes criteria for determining whether an item or service is a benefit available under Traditional Medicare…**"

Is CMS watching “Every Breath [David] Take[s]”? – The (b)(2) Examples

- “For example, this includes payment criteria for inpatient admissions at 42 CFR 412.3”
  - *This is the two-midnight rule.*
- “Services and procedures that the Secretary designates as requiring inpatient care under 42 CFR 419.22(n)”
  - *This is the inpatient only-list.*
- Requirements for payment of Skilled Nursing Facility Care, Home Health Services, and Inpatient Rehabilitation Facilities.

Can I Forward an E-Mail From Counsel to Other Employees?

- Yes, but it could destroy the attorney-client privilege.
- Assume all e-mails will be preserved forever.
- Communications should not be disclosed outside employees who need to know.
- When in doubt, pick up the phone or ask the lawyer if it's OK to forward.

What Happened in the *Supervalu* Case?

- *U.S. ex rel. Schutte v. SuperValu Inc*.
  - 9-0 decision (Justice Thomas authored)
  - The False Claims Act's scienter element — which asks whether a defendant "knowingly" submitted a "false" claim to the government — refers to a defendant's knowledge and subjective beliefs — not to what an objectively reasonable person may have known or believed.
- Narrow decision!

Do We Self-disclose to the OIG or USAO?

- Trick question! Report to the MAC.
- FYI:
  - *February 2023 the DOJ adopted new policy establishing voluntary self-disclosure credit in corporate criminal enforcement actions brought by U.S. Attorneys' Offices (USAO).*
  - *Friction between Office of Inspector General (OIG) and USAO reporting processes.*

How Far Back Should We Go On a Refund?

- Only have to refund an overpayment.
- Medicare can only reopen a claim for 48 months unless there is fraud of similar fault. If no fraud or similar fault, refund for 48 months.
- If, however, there is fraud or similar fault refund for 6 years.

I’m Considering Selling My Practice to Private Equity. What Do I Need to Know?

- There is a lot to think about.
- A sale can include an attractive purchase price, reduction in administrative work, and viable succession plan.
- It may involve a time-consuming due diligence process, less control over the operation of the practice, and a lower ceiling for future compensation.

My Partner Sells Goods/Services to Our Practice. Do We Need a Written Agreement?

- It depends.
- Does the partner make referrals of designated health services subject to the Stark law?
- A written agreement is a good idea, even if not required.

Does Creating a Business Entity Eliminate My Personal Liability?

- It won’t eliminate liability for a professional’s own malpractice or violations of law.
- Landlords, lenders and others may require personal guarantees.
- Can limit certain liabilities and provide tax benefits.

I’m Joining a Hospital and Closing My Practice. What Do I Need to Do?

- Work with patients to transition care.
- Notify payors, boards and licensing agencies.
- Arrange for custody of medical records.
- Pay all debts.
- Notify accountant and IRS.
- Dissolve the entity.

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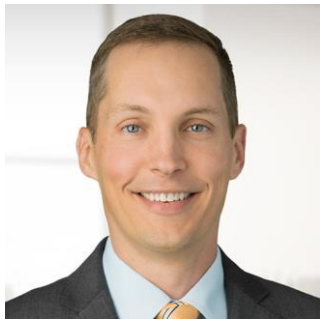

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