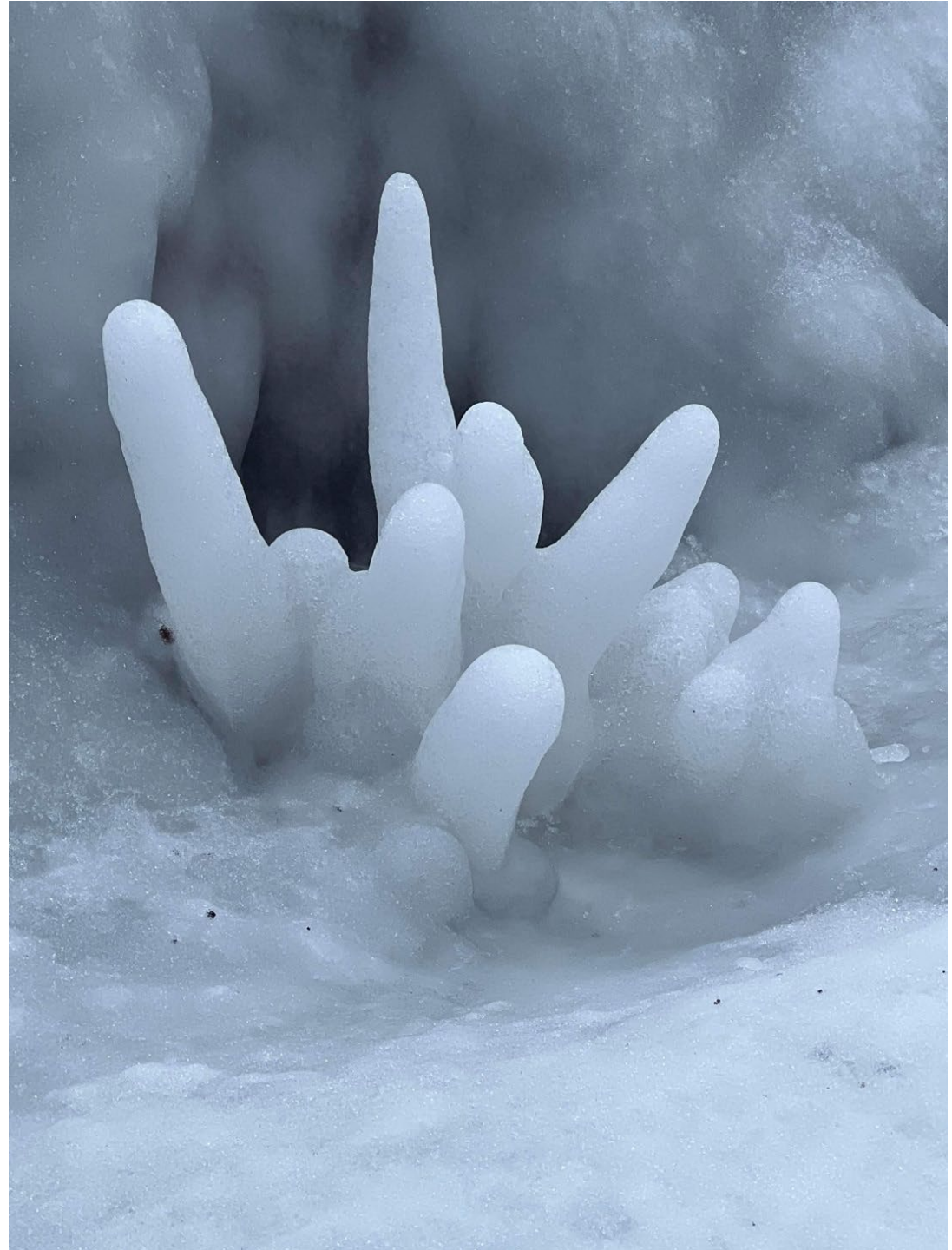
Relationship Advice for the Lawlorn

Health Law Webinar

February 14, 2024

Fredrikson

Where Law and Business Meet®



Announcements

- All of our webinars are recorded and stream for free HERE.
- The March 13 Webinar is about data.
- We read evaluations, and welcome topic suggestions.

Acronyms

- ASC = ambulatory surgical center
- CAM = Common Area and Maintenance
- CMP = civil monetary penalty
- DHS = designated health service
- JV = Joint Venture
- PHE =public health emergency

Laws Governing Relationships

- Medicare Antikickback statute.
- Stark.
- Civil Monetary Penalties.
- Tax Exemption rules (if applicable).
- State Antikickback, Stark, Fee Splitting Provisions, Supervision (and maybe CON).
- Medicare billing and supervision rules.
- False Claims Act? (Not really)
- The Golden Rule??

Stark

- Civil, not criminal. Intent doesn't matter. Applies when physician refers to an entity that provides Designated Health Services ("DHS.") Applies only to referrals for DHS, **but** it applies to **all** compensation. If there is compensation, must meet an exception.
- Applies even if the compensation isn't related to the DHS. If a physician is paid to be a consultant, and they order DHS you provide, it applies.

Referral Madness

Dear David,

I heard that if a physician says to a patient “you need an MRI. I own an MRI in this building, but please don’t go there to get your scan. Because of my financial relationship with the scanner, I need to be sure you go someplace else,” but the patient disregards the advice, and goes to the MRI owned by the physician, the physician referred the patient to his MRI. That can’t be true, right?

Stark

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- Applies even if the compensation isn't related to the DHS. If a physician is paid to be a consultant, and they order DHS you provide, it applies.
- **It's true! It's the plan of care, not the referral, that matters!**
- Be wary or relationships with grandparents, grandchildren, spouses and more.
- SSA 1887/42 U.S.C. 1395

“Designated Health Services”

- Clinical laboratory.
- Physical therapy.
- Occupational therapy.
- Radiology services.
- Radiation therapy services and supplies.
- Durable medical equipment and supplies.
- Parenteral and enteral nutrition.
- Prosthetics and orthotics.
- Home health services.
- Outpatient prescription drugs.
- Inpatient and outpatient hospital services.

Antikickback

- Felony. Intent controls. When “one purpose” of payment is to influence referrals for a federal health care program.
- Doesn’t apply to payments within an entity.
- 42 U.S. Code § 1320a–7b

56 F.R. 35952 (July 29, 1991)

“Comment: Many commenters requested the OIG to clarify that payments between corporations which have common ownership are not subject to the statute. Commenters cited as examples intracorporate discounts and payments between two wholly-owned subsidiaries. Some commenters argued that referral arrangements between two related corporations do not constitute "referrals" within the meaning of the statute, and suggested that the OIG define the word "referral" to exclude such activity.

Response: We agree that much of the activity described in these comments is either not covered by the statute or deserves safe harbor protection. We believe that the statute is not implicated when payments are transferred within a single entity, for example, from one division to another. Thus, no explicit safe harbor protection is needed for such payments.

Antikickback: Role of the Safeharbor

- They are narrow, but you don’t have to meet one.
- Consider the ASC safe harbor, 42 CFR 952.1001(r)(4)(viii): “The hospital may not be in a position to make or influence referrals directly or indirectly to any investor or the entity.”
- Think Annie Lennox or Taylor Swift: Tell me why!!

Civil Monetary Penalties

- Permits fines for payments that are “likely to influence” a beneficiary to order or receive services from a particular provider, practitioner, or supplier.
- 42 U.S.C. 1320a-7a

Tax Exemption

- “Private inurement” occurs when a person gets an undeserved benefit from a tax exempt organization.
- “Intermediate sanctions” allow the IRS to recoup the money, plus penalties, from the recipient.
- IRC 501(c)(3).

State Laws

- State antikickback laws -- may be broader than the federal law.
- Fee splitting -- may prohibit a physician from sharing revenues with nonphysicians, and/or physicians outside of the group except on the basis of work performed, but may not apply.
- Many states require disclosure. Some specify how. Better to overdisclose.

No Written Contract

Dear David,

We are a physician group providing coverage to a local hospital. They have had significant staffing issues and called us urgently to pitch hit. They agreed to pay us $1,000 a day. We traded emails outlining terms but we never signed a contract. The hospital has been paying us consistently for the last year. But their counsel now says this is a Stark problem because there is “no written contract” and we will need to refund all the money. Is that really true?

No Written Contract

- Question the premise. What constitutes a “written contract?”
- Changes to Stark in 2020 are very helpful.
- “Writing” can be satisfied by a collection of documents, including contemporaneous documents.
- Signature requirement can be satisfied by an electronic or other signature valid under Federal OR State law.
- Signatures obtained within 90 days are adequate.
- Don’t forget the new limited remuneration exception.

§411.354(e)

Limited Remuneration: 42 C.F.R. 411.357(z)

- Permits compensation up to $5,000 per calendar year, adjusted for inflation.
- Compensation can’t take into account volume and value of referrals/other business, can’t exceed FMV, must be commercially reasonably absent referrals, and, if a lease, not per click.
- If remuneration is conditioned on referrals, must meet 411.354(d)(4).
- Applies to employees and locum physicians.

What Constitutes Evidence?

- Informal communication via email or text.
- Internal notes to file.
- Similar payments between the parties from prior arrangements.
- Generally applicable schedules.
- Other documents recording similar payments to or from other similarly situated physicians for similar services.

85 FR 77492, 77592

Changes

Dear David,

David Bowie, M.D., provides medical director services to us under a multi-year agreement we signed six months ago. In light of a recent burst of inflation we would like to increase the rate of pay. Our understanding is that Stark does not permit this because you can't change the terms during the first year. Oh, Dr. Bowie struggles with time records. "Time may change me, but I can't trace time" he says.

Changes

- “Compensation (or a formula for determining the compensation) that is modified at any time during the course of a compensation arrangement, including the first 90 days of the arrangement, satisfies the set in advance requirement of various exceptions only if all of the following conditions are met: …
- Prospective changes are permissible as long as they still meet the Stark exception.

85 F.R. 77594

Getting a Record Deal

- Stark doesn’t explicitly require time records.
- Clearly having them is useful.
- Your agreement can impose a higher burden than the law. Is a detailed agreement always helpful???

Our Mistake but Their Problem?

Dear David,

We are a hospital leasing space to several physician groups. Our AR team goofed and failed to send an invoice to the physicians for CAM for the last decade. We have just discovered the problem. It's totally our mistake. Must we collect from the physicians? Is this a Stark problem? Do we need to self-disclose?

Our Mistake but Their Problem?

- It is pretty clear the hospital cannot recover all of the CAM.
- If the lease is still in place, Stark offers considerably more flexibility.
- If the lease is complete or the physicians are unwilling to strike any compromise, a self-disclosure might be appropriate.

Our Mistake but Their Problem?

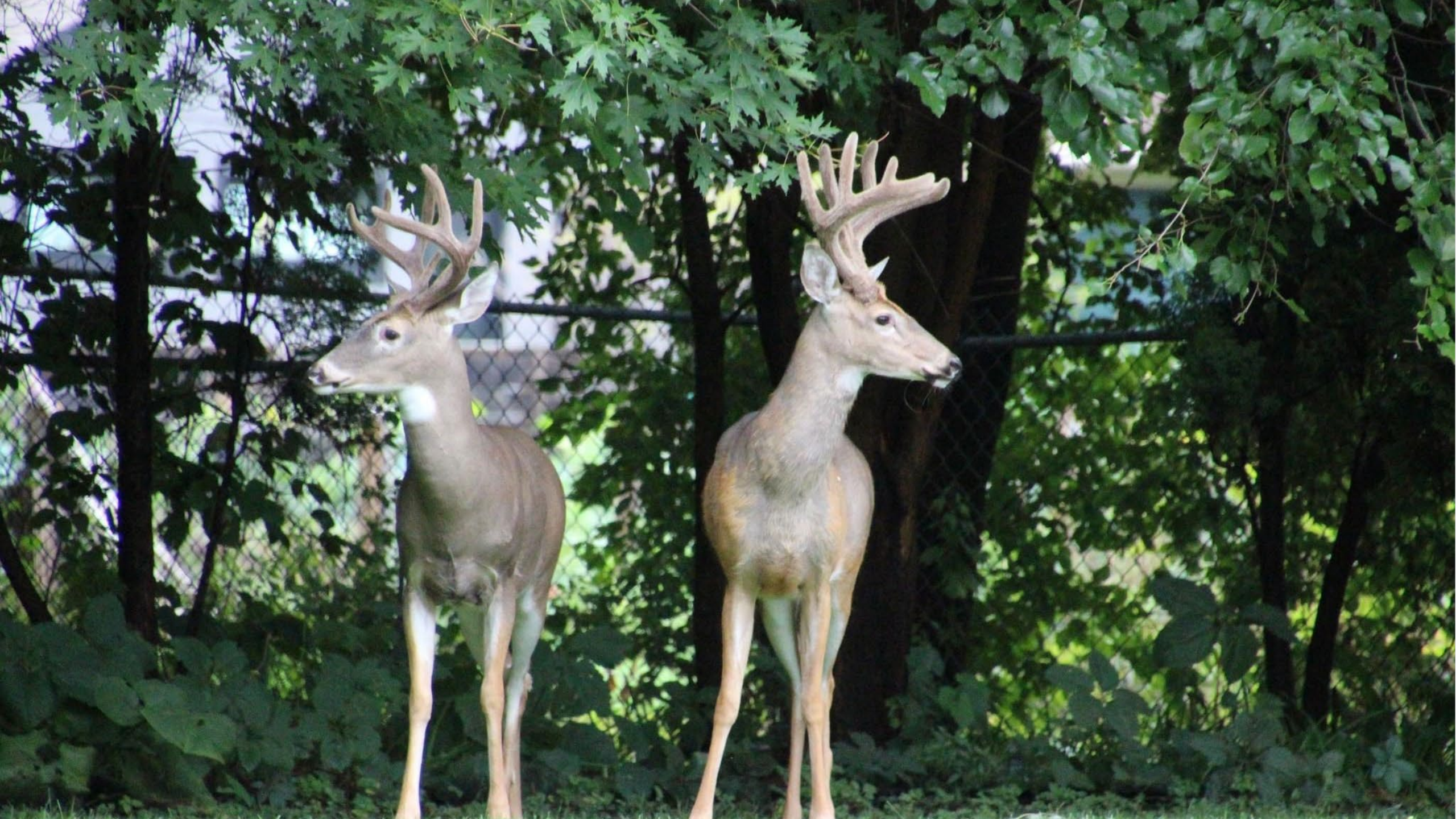
- Hesitation to allow “unringing the bell.”
- Rejected the idea of 90 days after the comp. Opted for “facts and circumstances.”
- Could there be a more compelling argument for auto-renew???

Page 77583

Leverage, Baby

Deer David,

We are the largest OB group in the country. We have a foundation that promotes maternal health and encourages patients to obtain prenatal care. Most hospitals have agreed to contribute to that foundation, but one hospital stubbornly refuses. Obviously, we will threaten to take our deliveries elsewhere, what else can we do to bring the hospital around?



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Leverage, Baby

- Has our writer admitted to a felony?
- Is a gift to charity “remuneration”?
- Is this a legitimate charity?
- Must your advice columnist call 911?

Paying the Piper

Dear David,

We are a device company with a novel urologic product. We need to explain how the product works. We want to compensate the physician with the most experience with our product in each state to serve as a spokesperson. Can we?

Paying the Piper

- How would the government rewrite that question?
- How does the device company demonstrate referrals were not a factor in the selection process?
- How can we achieve the same result with far less risk?
- I would much prefer a very small number of physicians paid handsomely for speaking than a cadre each minimally compensated.

Incentivize (or Incentiveknees?)

Our orthopedic clinic wants to make sure employed physicians are using the clinic's ancillaries. We want to offer a bonus of $100 for every patient they refer to our physical therapy department. The clinic owns 60% of an ASC in a JV with a hospital. We want to give the physician's production credit for the surgeries they do at the ASC. We also want to pay our administrative staff $10 for every MRI they schedule on our equipment.

Incentivize, (or Incentiveknees?)

- PT and imaging are DHS under Stark. ASC's are not.
- A recent advisory opinion , 23-07 confirms productivity payments for an ASC are permissible.
- "Can" and "should" are very different.

BOGO

Dear David,

A device company has offered us pricing with a volume discount. If we buy four of their product, we get the fifth for free. We would love to take them up on this, but we are pretty sure it is a kickback. Is it?

BOGO

- Does a kickback require a deceived third party?
- One vendor sells items at $25 each, with a buy four-get-the-fifth-free. A second sells the same items $20 each. Are they analytically different?

Customer Service Discount

Dear David,

A patient had a terrible outcome. While we do not believe our care was the source of the problem, as a risk management tool, we would like to waive the beneficiary liable portion of their care. I have heard waiving a co-payment is fraud. Must we bill this patient?

Customer Service Discount

- Consider the Anti-Kickback Statute (induce) and CMP (influence) and state law.
- What is the intent of the payment?
- Must you worry about Section 111?
- Tell your malpractice carrier.

Flubbed Phlebotomist?

Dear David,

As a laboratory, we feel like it is our responsibility to get blood samples. We want to place phlebotomists at busy clinics. Obviously, since we will be in clinic space, we will need to pay them rent. The person won't be that busy, so we would like to offer to have that person assist the clinic with simple administrative tasks. That will save the clinic from hiring more staff. Since this strategy lowers healthcare costs, it's legal, right?

Flubbed Phlebotomist?

- What is the most problematic phrase in the letter?
- What healthcare costs are saved?
- The writer's premise is reasonable. With proper execution, labs can place Phlebotomists. But care is needed.

Take a Chance?

Dear David,

It is pretty brutal being an independent physician group right now. There is one other group of our specialty 90 miles away. We have both been considering selling to various health systems, but think that if we were to merge, we could stay independent. But merging would make us a monopoly, right?

Take a Chance?

- Antitrust analysis has a strong policy component.
- Consider the geographic and product markets.
- Who are your competitors?
- What are the barriers to entry?
- The market is not just independent groups.
- In the current climate, mergers of independent physicians might be pro-competitive.

No Medicare, No Risk?

Dear David,

We are planning to set up a joint venture with physician groups across the country. We're risk adverse so we're planning to exclude Medicare and Medicaid patients from the joint venture. We will still bill Medicare for the services, but we will exclude that revenue from the joint venture. Why don't we hear you promoting this risk-free idea?

No Medicare, No Risk

- Remember than payments for things unrelated to governmental patients can still be considered kickbacks.
- The government routinely states offering excess money for privately insured patients can induce Medicare referrals.
- Beware of the state law trap. If state law mirrors federal law, a program excluding Medicare and Medicaid patients can be easily attacked. Excluding Medicare and Medicaid almost constitutes an admission.

Bill Bill for the Billboard?

Dear David,

A top cardiac surgeon has recently joined our medical staff. We want to promote this on billboards across the region. We plan to feature Dr. Bill Jones prominently, touting both his high quality metrics and our Door to Cath time. Can we do this?

Bill Bill for the Billboard?

- Promoting employees is very low risk.
- Independent medical staff present a bigger challenge.
  - Joint marketing is permissible.
  - Promoting a physician is likely problematic.
  - Promoting the program, without promoting the physician, is defensible.

I’m Sorry I Asked

Dear David,

We are considering putting an MRI in our clinic. I know that there are some Stark issues and that Stark is hard. We have a lower who charges a low hourly rate ($350) who sent us a ten page letter explaining that we can’t have the MRI in our clinic. The charge for the letter was $10,000. What should we do?

I’m Sorry I Asked

- Hourly rates are irrelevant. Total bills are what matters.
- Ten page answers are rarely helpful.
- My relationship advice: choose counsel who make your life better, not worse.

Cost Containment

Dear David,

Post-PHE labor costs are through the roof. We cannot keep functioning like this. We would like to sit down with our state hospital association and establish recommended salary rates for various positions. Hospitals wouldn't be required to comply with the recommendations, but we suspect everyone would happily follow them. Do you see any issues with this plan?

Cost Containment

- Antitrust laws can apply to employers.
- Agreements on price can actually be criminal.
- The government views salary-related issues as an enforcement priority.
- Implicit agreement is sufficient to support antitrust violations.

Help Going It Alone

Dear David,

We are an independent physician practice. We like our autonomy and would very much like to remain independent. However, we could use some capital investment. What are our options?

Help Going It Alone

- Traditional bank loan.
- Private equity.
- Hospital investment in the practice.
- Create an MSO.
- Value-based options.

Saying Thank You

Dear David,

We’re a startup healthcare facility and we rely heavily on word of mouth. We are very grateful when someone recommends our organization. We like to send thank you gifts like a couple of hundred dollars or two free visits at our clinic. Can we?

Hard to Say I’m Sorry

- Beware of the e-clinical works settlement.
- That’s only a settlement, but makes the government’s position clear.

Things Can Only Get Better

Dear David,

We are determined to have the best hospital in the region. To get there, we'll need help from physicians. We want to be fair and pay them for their work. We've heard that you can do gain sharing or co-management. First, what's the difference between the two of them? Second, is it legal? Third, we've heard that it's improper to do this with our employed physicians and that we can offer gain sharing to independent physicians. Is that true?

Things Can Only Get Better

- Over a dozen advisory opinions endorse co-management. The OIG's position flipped in 2001.
- Choose your words carefully.
- Choose metrics carefully.
- If anything, the risk with employed physicians is lower!

Teacher, Teacher

Dear David,

We are a medical device/imaging/medical equipment company, and we have a new product. In order to teach people how to use the product, we want to bring them to a well-known academic medical center where they can see our product in action. Obviously, we need to make sure the medical center is compensated for their work. Can we?

Teacher, Teacher

- Absolutely but …
- Determining a value here can be difficult. One obvious measure: lost efficiency.

Value Pack

Dear David,

We’re restructuring a value-based arrangement. Our arrangement won’t feature down-side risk. Our counsel told us that we can only use in-kind reimbursement because otherwise we won’t fit within the Medicare anti-kickback safe harbor. Your thoughts?

Value Pack

- Get new counsel.
- Anti-kickback safe harbors are extraordinarily narrow. Understand the ASC safe harbor, which only protects ASC JVs outside the hospital's service area.
- Kickback is all about intent. It's only Stark where you must meet an exception.

SNF, SNF, Cry, Cry

Dear David,

We have so many people in the hospital who should be somewhere else. We really need help from our local SNFs. Someone proposed a bed reserve agreement with the SNFs, but I am worried that someone will say we are paying for referrals so I am hesitant to do that. Your thoughts?

SNF, SNF, Cry, Cry

- Unless the SNF is physician-owned, Stark is irrelevant.
- The kickback analysis: Can someone legitimately claim you are paying the SNF for referrals?
- What facts would support that claim? Do hospitals want SNF referrals right now?

Data Lor(e)

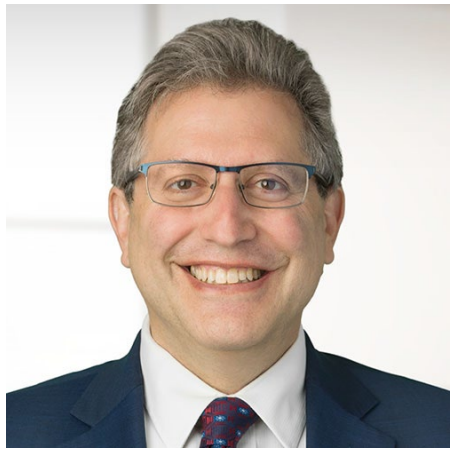
Dear David,

We've been approached by a company eager to mine our patient data. They're offering substantial money to us. Times are tough and we'd really like to take it. Can we?

Data Lor(e)

- This is why I have colleagues!
- Tune in next month.
- Spoiler alert: there are lots of issues.

Presenter



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Thank you!

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