2022 Virtual Regulatory Review Series

Fraud & Abuse: 2021 Year in Review

Stark and AKS Updates

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Today's Presenters and Agenda

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- Agenda
  - Fraud & Abuse Year in Review
  - Stark & AKS Updates

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For CLE questions, contact Sinead McGuire, Polsinelli department marketing manager, at smcguire@polsinelli.com.

Settlement Trends

- **Alleged kickbacks**
  - So. Carolina Pain Management Clinics, Drug Testing Laboratories and a Substance Abuse Counseling: $140M
    - Arrangements to induce referrals of urine drug tests
  - Prime Healthcare and two doctors: $37.5M
    - Allegations of kickbacks, billing for a suspended doctor, and false claims for implantable medical hardware
  - Athena Health: $18.25M
    - Free tickets to sporting events, luxury travel, meals and alcohol to generate sales of its EHR product
  - Neurosurgeon & 2 medical device distributors: $4.4M
    - Paid to induce use of medical devices and received kickbacks

What Happened in 2021?

- **Alleged patient inducements**
  - Oglethorpe Inc.: $10.25M
    - Three facilities provided free transportation to patients to induce their business and admitted patients who did not require psychiatric treatment.
  - Arriva Medical LLC and Alere: $160M
    - Medicare mail-order diabetic testing supplier
    - Kickbacks were paid to Medicare beneficiaries; patients were ineligible to receive meters

Settlement Trends

- **<u>Medical device manufacturers settlements</u>**
  - Alere Inc.: $38.75 million
    - Sold defective blood coagulation monitors allegedly causing a dozen deaths and hundreds of injuries
  - St. Jude: $27 million
    - Sold defective heart devices
  - Athrex: $16 million
    - Paid kickbacks to an orthopedic surgeon in the form of royalties

Settlement Trends

- **Hospitals**
  - University of Miami: $22M
    - Alleged provider-based deficiencies and unnecessary laboratory tests for transplant cases
  - Akron General Hospital: $21.25M
    - Alleged Stark Law violations for above FMV compensation
  - Ascension Health (Michigan): $2.8M
    - Alleged unnecessary procedures by gynecologic oncologist
  - San Mateo County Medical Center: $11.4M
    - Alleged unnecessary admissions

Court Decisions

Court Rulings

- ***U.S. ex rel. Lutz v. Mallory***, 988 F.3d 730 (4th Cir.)
  - Defendant lab used independent contractor sales reps and paid commissions based upon lab volume
  - Fourth Circuit affirmed jury verdict and held that independent contractor sales activities fall within the AKS
  - Implication: independent contractor sales reps now *per se* unlawful in Fourth Circuit?
    - DOJ press release appears to characterize all commission-based arrangements as prohibited under AKS
  - Case of "bad facts make bad law"?
    - Defendants were warned about potential AKS Violation
      - Parties' attorneys and outside attorneys

Court Rulings

- ***Integra Med Analytics LLC v. Providence Health & Services,*** 854 Fed. Appx. 840 (9th Cir.)
- Hospital system engaged consultant to improve Medicare billing
- Relator claimed that statistical "outlier" data shows overbilling
- Court: relator failed to state claim for FCA violation because of the obvious ***alternative explanation*** that defendants were more effective at properly coding for reimbursement than others
  - "We need not accept the conclusion that the defendant engaged in unlawful conduct when its actions are in line with lawful 'rational and competitive business strategy.'"

Court Rulings

- ***U.S. ex rel. Shutte v. SuperValu, Inc.***, 9 F.4th 455 (7th Cir. 2021)
- Seventh Circuit ruling on question of reasonable interpretation of ambiguous legal requirements
- A defendant who acted under an incorrect interpretation of the relevant statute or regulation did not act "knowingly" if
  - (1) interpretation was objectively reasonable, and
  - (2) no authoritative guidance cautioned defendants against it
- Following adoption by five other Circuits, but other Circuits have applied different standards

Other Court Developments

- ***Johnson v. Bethany Hospice and Palliative Care LLC***, 853 Fed. Appx. 496 (11th Cir.) *cert. granted,* No. 21-462 (U.S.)
  - U.S. Supreme Court granted certiorari
    - Jan 18, 2021: US Solicitor General invited to submit brief
  - Issue: whether relator must present not only the particulars of an alleged fraud scheme, but plead specific details for payments
  - Relator claimed that hospice paid kickbacks to physicians
  - Relator claimed that *all* patient were covered by Medicare and *all* patients came from a physician who received kickbacks, but relator did not identify specific claims that were false
  - Eleventh Circuit upheld dismissal because relator did not explain which claims were false and cannot "rely on mathematical probability to conclude that [a defendant] surely must have submitted a false claim at some point."

Court Rulings

- *Winninger v. Kirchner*, 2021 CO 47 (June 2021)
  - 18-4-405: crime of “theft, robbery or burglary”
  - 18-4-414: crime of “theft of medical record”
  - But 405 also has private civil right of action; 414 does not
- Conclusion: a “theft of medical record” under 414 is not automatically a “theft” under 405
- Implication: no private right of action for theft of medical record

Other Developments

OIG Self-Referral Disclosure Protocol

- OIG updated Self-Disclosure Protocol on Nov. 8, 2021
- Name change: “OIG’s Health Care Fraud Self-Disclosure Protocol”
  - Distinguished from OIG’s Grant Self-Disclosure Program and the OIG’s Contractor Self-Disclosure Program
- Minimum settlement doubled
  - Kickbacks: from $50,000 to $100,000
  - All other matters: from $10,000 to $20,000
- OIG will no longer advocate for disclosing parties in criminal matters (civil matters only)
- Initial submission must itemize damages by health care program
- Electronic submission through OIG’s website required

Focus on Joint Ventures

- OIG Advisory Opinion 21-18
  - Concluding joint venture arrangement posed a significant risk of being used as a vehicle to reward the JV partner for directing business to JV
- Flowers Mount Hospital settled for $18.2M
  - Alleged that physician-owned hospital conditioned investment on referrals to hospital (and required physicians to retire and sell share to younger physicians)
- Ambulatory Anesthesia of Atlanta settled for $28M
  - JV of ASC and anesthesia providers alleged to provide kickbacks
- Bethany Hospice (above)
  - 11 Cir. dismissed claims based upon JV of hospice with referring physicians

The Brand Memo is Dead

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Office of the Attorney General
Washington, D. C. 20530
July 1, 2021

MEMORANDUM FOR: HEADS OF ALL DEPARTMENT COMPONENTS

FROM: THE ATTORNEY GENERAL

SUBJECT: ISSUANCE AND USE OF GUIDANCE DOCUMENTS BY THE DEPARTMENT OF JUSTICE

This Memorandum revises and clarifies the principles that should govern the issuance and use of guidance documents by the Department of Justice.

- Brand Memo rescinded July 1, 2021 via the Garland Memo
- Garland Memo:
  - Criticizes Brand Memo as overly restrictive, discouraging the development of valuable guidance, creating collateral disputes, and hampering DOJ attorneys
  - Concedes that agency guidance alone never forms the basis for enforcement
  - Expressly authorizes DOJ attorneys to use relevant guidance documents "in any appropriate and lawful circumstances" (e.g., when a guidance document may be entitled to deference or carry persuasive weight and where guidance documents are relevant to claims or defenses)

COVID-19 Enforcement

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Office of the Attorney General
Washington, D. C. 20530

May 17, 2021

MEMORANDUM FOR THE DEPUTY ATTORNEY GENERAL
HEADS OF DEPARTMENT LITIGATING COMPONENTS
UNITED STATES ATTORNEYS
EXECUTIVE OFFICE FOR UNITED STATES ATTORNEYS
FEDERAL BUREAU OF INVESTIGATION
OFFICE OF THE INSPECTOR GENERAL
ORGANIZED CRIME DRUG ENFORCEMENT TASK FORCE
INTERPOL WASHINGTON

FROM: THE ATTORNEY GENERAL

SUBJECT: COVID-19 FRAUD ENFORCEMENT TASK FORCE

Over the past year, the Department of Justice has led an historic enforcement initiative to detect and disrupt COVID-19 related fraud, charging nearly 600 defendants to date with crimes involving over $600 million in 56 federal districts around the country. The Department has secured civil injunctions

Corporate Practice of Medicine?

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- American Academy of Emergency Medicine Physician Group sued Envision Healthcare (Dec. 2021)
  - Alleges Envision Healthcare violated state law by "taking over" emergency department operations at Placentia (Calif.) Linda Hospital, including violation of California corporate practice of medicine prohibition
    - Envision Healthcare is a large emergency medicine group with operations at 540 facilities in 45 states
- Unpublished statement from Colorado Medical Board (2021)
  - "Provider network" law requires that all owners of a Colorado provider network must be licensed health care providers (*i.e.,* layperson ownership is prohibited)

Polling #1

Question: True/False: There are no cases of potential interest to hospitals before the U.S. Supreme Court in the current term.

Answer: False

Stark and AKS Updates:
What You May Have Missed in the COVID Haze

Agenda

- What are we talking about, and why?
- Stark Updates
- AKS Updates
- Value-Based Arrangements
- What Next?

We're Not Talking About…

- Temporary COVID Blanket Waiver for Stark/AKS Compliance
- Guidance issued by CMS/OIG in March/April 2020
- Flexibility available through the end of the public health emergency
- For more information:
  - https://www.cms.gov/files/document/covid-19-blanket-waivers-section-1877g.pdf
  - https://www.cms.gov/files/document/explanatory-guidance-march-30-2020-blanket-waivers-section-1877g-social-security-act.pdf
  - https://oig.hhs.gov/coronavirus/OIG-Policy-Statement-4.3.20.pdf

Do We Still Care?

- Yes.
- Enforcement is likely to pick up as enforcement teams return to the office
- In the last few months:
  - Bayada Home Health - $17M FCA/AKS Settlement (Sept. 2021)
  - Panda Conservation Group (Laboratory) – Guilty Plea $73M kickback conspiracy (Sept. 2021)
  - Alliance Family of Companies (EEG Testing) - $15.3M AKS Settlement (July 2021)
  - Prime Healthcare - $37.5M Settlement (July 2021)
  - Akron General Health System $21M Settlement (Stark) (July 2021)

Timeline

- Final rules from CMS and OIG arrived December 2, 2020, to be effective (mostly) in January 2021
  - Aimed to Remove Regulatory Barriers to Innovation
  - Encourage Participation in Value-Based Arrangements
  - Clarification and Simplification of Existing Rules
  - (Attempted) alignment between Stark and AKS requirements
  - Significant Focus on Social Determinants of Health In OIG Commentary
- Final Rule from CMS – November 2021
  - Indirect compensation/unit-based compensation updates

Stark Updates

- Commercial Reasonableness gets its due:
  - Must further a legitimate business purpose and be sensible when considering the characteristics of the parties, including size, scope, and specialty
  - Losing money does not automatically mean the arrangement is not commercially reasonable

- Key points and considerations:
  - Commercially reasonable means what we thought it meant – but important clarity that profit is not required
  - Cannot "rubber stamp" commercial reasonableness

Commercially reasonable means that the particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty. An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties.

Stark Updates

- "Volume or value" and "other business generated"
  - New guidance regarding when compensation will take into account the "volume or value" of referrals or "other business generated"
  - Clarification regarding productivity-based compensation for hospital/physician arrangements
- Key points and considerations:
  - CMS sought a "bright line" rule for this standard

Compensation from an entity furnishing designated health services to a physician (or immediate family member of the physician) takes into account the volume or value of referrals [or other business generated] only if the formula used to calculate the physician's (or immediate family member's) compensation includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with the number or value of the physician's referrals to [or other business generated for] the entity.
42 C.F.R. § 411.354(d)(5).

[Same standard for compensation paid *by* a physician, but with negative correlation between referrals and compensation]

Stark Updates

- Group practice profit shares and productivity bonuses
  - No split pooling of DHS profits based on service line – pools must be based on all profits of the group (or ≥ 5 physician component)
  - Groups may allocate DHS profits based on physician's participation in a value-based enterprise
  - Effective January 1, 2022

- Key points and considerations:
  - These rules are technical, but the takeaway is that it may be necessary to review existing contracts to confirm physician group compensation complies with the new rules

Stark Updates

- Limited remuneration to a physician
  - New exception! 42 CFR 411.357(z)
  - Up to $5,000 per physician per calendar year (adjusted for inflation) for the provision of items or services
  - No written agreement required
  - Must be FMV and commercially reasonable
  - Limitations on percentage-based and per-unit methodologies if applying this exception to lease/use of office space or equipment

- Key points and considerations:
  - This may solve smaller Stark problems you encounter

Stark Updates

- Donation of cybersecurity technology and related services
  - New exception/safe harbor!
    - 42 CFR § 411.357(bb) (and 1001.952(jj) for the AKS)
    - Must be in writing
    - Cannot take into account referrals or other business generated
    - Physician or physician's practice cannot make the receipt or amount of the donation a condition of doing business with the donor
    - Unlike EHR donation – no contribution from recipient required
    - AKS specifically prohibits cost-shifting to federal health care programs
- Key points and considerations:
  - Provides opportunity for hospitals and other providers to donate helpful technology to community physicians

Stark Updates

- EHR donation exception
  - Removal of sunset provision – now a permanent exception
  - 15% recipient (physician) contribution lives on
  - Permits donations of upgrades/replacement systems
  - Similar changes under the AKS
- Key points and considerations:
  - This has been a valuable exception allowing technology donations to community physicians
  - Removal of sunset provision means that hospitals can continue to implement EHR donation programs

Stark Updates

- Isolated financial transactions
  - New definition – 42 CFR 411.351
  - CMS clarified the use of this exception – does not protect a single payment for multiple or repeated services
- Key points and considerations:
  - Due to perceived abuse of this exception, parties should be more cautious in how they use this exception to solve potential disputes
  - Unclear what constitutes a “bona fide dispute”

Stark Updates

- Special rules for reconciling compensation
  - 42 C.F.R. 411.353(h)
  - Allows parties to true up mistakes in compensation during the term of the agreement and up to 90 days following the termination or expiration of the agreement
  - Related changes to definition of “period of disallowance”
- Key points and considerations:
  - Useful rule for correcting mistakes in compensation

Stark Updates

- Other Interesting Changes:
  - DHS exclusion for certain services subject to prospective payment systems
  - Exclusion of “titular” ownership interests
  - Confirmed validity of electronic signatures
  - 90-day grace period for writing requirement
  - Non-exclusive rental arrangements
  - Removal of most AKS compliance requirements
  - Payments by a physician exception
  - Signature flexibility for physician recruitment exception
  - NPP patient care services/recruitment support

AKS Updates

- Personal services and management contracts
  - Aggregate compensation not required to be set in advance, but methodology for determining compensation must be set in advance
  - Removal of requirement that part time arrangements specifically identify schedules and charges for each interval
  - Clarifications for payments based on outcomes
    - Payments are protected if based on credible measures supported by appropriate benchmark data (among other conditions)
    - Certain entities are excluded from safe harbor protection
- Key points and considerations:
  - Arrangements are now more likely to qualify for safe harbor protection

AKS Updates

- Local transportation safe harbor
  - Expanded mileage limits for rural areas (75 miles)
  - Eliminates mileage limitations for transporting patients back to residences
  - Affirmed acceptance of rideshare arrangements
  - OIG did not extend safe harbor protection to:
    - Transportation other than to a residence (e.g., to another health care facility)
    - Health-related, but non-medical transportation
- Key points and considerations:
  - Greater flexibility for a safe harbor that facilitates patient access to care

Overview of Value-Based Changes (and Alignment)

Stark	AKS
VBA - Full Financial Risk (New) (42 CFR 411.357(aa)(1))	VBA with Full Financial Risk (New) (42 CFR 1001.952(gg)).
VBA - Meaningful Downside Risk to Physician (New) (42 CFR 411.357(aa)(2))	VBA with Substantial Downside Financial Risk to Value-Based Enterprise (New) (42 CFR 1001.952(ff));
Value-Based Arrangements (New) (42 CFR 411.357(aa)(3))	Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency (New) (42 CFR 1001.952(ee))
	Patient Engagement and Support (New) (42 CFR 1001.952(hh))
Indirect Compensation Arrangements (Changes) 42 CFR 411.354(c)(2)	
	Personal Services Arrangements (Changes) (42 CFR 1001.952(d)
Group practice (allocation of value-based reserve) (Change Eff. Jan 1, 2022 (42 CFR 411.352(i)(3)	

Key Definitions

Coordinating and Managing Care (AKS Only): Deliberate organization of patient care activities and sharing of information [between VBE/VBE Participants/patients] designed to achieve safer, more effective, or more efficient care to improve the health outcomes of the target patient population.

Target Patient Population: Identified patient population using "legitimate and verifiable" criteria set out in advance in writing (and that further the VBE's value-based purpose)

Value-Based Activity: Includes: provision of item or service; taking of action; or refraining from action – must be in service of at least one value-based purpose (note: this excludes referrals, but AKS/Stark treatment is different)

Value-Based Arrangement: Arrangement for at least one value-based activity for the target patient population between or among the Value-Based Enterprise (VBE) and VBE participants

Key Definitions

Value-Based Enterprise:

- Two or more VBE participants—each of which is a party to a value-based arrangement with other VBE participant(s)—collaborating to achieve at least one value-based purpose
- Accountable body / person responsible for financial and operational oversight
- "Governing document"

Value-Based Purpose:

- Coordinating and managing care
- Improving quality of care (maintenance of quality of care is insufficient on its own)
- Reducing costs / growth in expenditures without reducing quality
- Transitioning from system of volume to value

VBE Participants: individual / entity engaging in at least one value-based activity in VBE

- AKS Safe Harbors exclude pharma manufacturers; DMEPOS manufacturers, distributors, suppliers; labs; others
- AKS definition *excludes* patients from definition of VBE Participant

Examples of Value Based Definitions

- **OIG Examples:**
  - VBE participant provides health technology under a value-based arrangement for recipient to use to track patient data in order to spot trends in health care needs and to improve patient care planning
  - VBE Participant provides care coordinator who works with recipient to help transition certain patients between care settings
  - Fitness tracker for patients - may constitute a value-based activity, if doing so is reasonably designed to achieve a value-based purpose
- **CMS Examples:**
  - Value-Based Activity: Routine post-discharge meetings between hospital and physician primarily responsible for patient's care post-lower extremity joint replacement procedures
    - CMS otherwise declined to provide a list of appropriate activities – did not want to artificially limit innovation

Tiers of Risk

The new Stark exceptions and AKS safe harbors that protect remuneration in the context of Value-Based arrangements are categorized based on the following tiers of downside risk:

- No Risk
- Meaningful Risk (Stark) or Substantial Downside Risk (AKS)
- Full Risk

Value-Based Arrangements – Value-Based / *Care Coordination Arrangements (No risk)*

Key Requirements

- Key terms in writing, signed by parties (remuneration set in advance)
- No inducement to reduce/limit medically necessary services
- Patient choice/physician's ability to act in best interest of patients
- No condition re referrals of non-target population or non-VBA business
- Ongoing monitoring/pruning of value-based activities (with specific deadlines)

Stark/AKS Distinction: AKS Safe Harbor *applies only to non-monetary remuneration*

Other distinctions:

AKS Safe Harbor

- VBE Participant must pay at least 15% of offeror's cost
- Terms must specify at least one specific, evidence-based outcome measure
- Marketing or patient recruitment activities prohibited
- "Limited technology participants" cannot condition remuneration on exclusive use or minimum purchases

"**Remuneration**:"

- **AKS**: *used predominantly to engage* in VB activities *directly related* to care coordination / target population health management; no more than incidental benefit to those outside the target patient population
- **Stark**: *for / results from* value-based activities for target patient population

Value-Based Arrangements – *Substantial (Meaningful) Downside Risk*

Substantial (Meaningful) Downside Financial Risk

*Exception/safe harbor applies to **remuneration**; "**not ownership / investment**"*

Key Distinctions relate to what is "**meaningful downside risk**"

Stark Exception:

Physician must repay VB entity or forgo at least 10% value of remuneration received for failure to achieve VB purpose

AKS Safe Harbor requires:

- **Substantial Downside Financial Risk *to the VBE*:** *3 options:*
  - financial risk of at least 30% of any loss on all covered items and services;
  - financial risk of at least 20% of any loss on a defined clinical episode of care; or
  - VBE's receipt of prospective per-patient payment for predefined set of items/services furnished to target patient population.
- **Meaningful share *of risk held by a VBE Participant*:** *2 options:*
  - VBE Participant assumes two-sided risk for at least 5 percent of the losses and savings, as applicable, realized by VBE pursuant to assumption of substantial downside financial risk; or
  - VBE Participant receives from VBE a prospective per-patient payment for predefined set of items/services furnished to the target patient population and does not otherwise claim payment for such items and services
- Remuneration must be directly connected to at least one of VBE's value-based purposes, or used predominantly to engage in value-based activities connected to items/services for which the VBE has assumed substantial downside financial risk
- Losses must be calculated using *bona fide* benchmarks

Other Issues: Requirements are similar to Care Coordination AKS Safe Harbor / Value-Based Arrangement Stark Exception; AKS Safe Harbor allows 6 month "phase-in" period; AKS Safe Harbor does not protect downstream

Full Financial Risk

Full Financial Risk VB Arrangements

- Protects in-kind or monetary remuneration (excluding ownership/investment interests or related distributions) between VBE and a VBE participant if VBE has **assumed full financial risk from a payor** (within 12 months)
- Does not apply to arrangements covering less than all items/services (e.g., episode of care)

AKS:

- **Full Financial Risk:** VBE is financially responsible on ***prospective basis*** for cost of all items and services covered by payor for each patient in target patient population for specified term (VBE Participant cannot look to payor for payment, must look to VBE)
- **Requires a Connection to Value-Based Purposes:** Remuneration exchanged between VBE and VBE Participant under must be connected to one or more value-based purposes but need not be connected to the purpose of coordinating / managing care for the target patient population
- **Quality and Utilization Review:** VBE must establish quality assurance programs to protect against underutilization and assess the quality of care for target patient population

Stark:

- **Full Financial Risk**: VBE is financially responsible on a ***prospective basis*** for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time
- **Remuneration Unrelated to Target Population Not Protected:** does not protect remuneration unrelated to the target patient population, such as general marketing or sales arrangements, though CMS does note that the remuneration itself could be used for the benefit of patients that are not part of target patient population

AKS – Patient Engagement Tools and Support

- Applies to arrangements between VBE Participants and *patients in a target patient population*
  - Must be in-kind remuneration (no cash) and directly connected to coordination and management of care
  - Must advance specific goals (i.e., adherence to drug/treatment regimens or care plans; disease management or prevention; or patient safety)
  - Value cap of $500/year
  - Recommended by the patient's licensed health care professional
  - No selection/discrimination based on payor
  - Other conditions/limitations apply
- Intent to promote patient adoption of technology and devices to promote value-based purposes (including addressing social determinants of health)
  - Examples could include: transit vouchers or rideshares; physical or structural modification to a patient's home to allow them to remain there; exercise or fitness equipment; equipment to facilitate telehealth interaction with providers

AKS – CMS-Sponsored Models

- OIG published a new safe harbor for participation in CMS-Sponsored Models and CMS-Sponsored Model Patient Incentives
- Intended to promote uniformity across models – but new Safe Harbor does not supersede or interfere with existing waivers
- If you're unclear on protection under waivers, consider whether the new Safe Harbor is helpful

Keys to VB Stark/AKS Compliance

- Lots of potential pitfalls – particularly for the no-risk exception/safe harbor
- Meet the definitions – these new exceptions/safe harbors are only available to VBE Participants in the same VBE
- Only apply to compensation arrangements – not ownership/investment
- Set up your VBE correctly – governing documents and accountability matter, as do clear objectives
- Watch out for differences between Stark & AKS flexibility
  - Exclusions from definition of VBE Participant
  - AKS – generally more narrow
- Maintain records for at least six years
- Beware of hidden pitfalls:
  - Inappropriate risk mitigation
  - State business of insurance issues

Polling #2

Question: True/False: The new value-based arrangement exceptions and safe harbors are easy to use and will be no challenge at all to implement.

Answer: False

2022 Stark Updates

- Indirect Compensation
  - CMS did not finalize a proposal to include in the definition of indirect compensation *any* compensation that is based on something other than a physician's personally performed services
  - CMS did finalize a proposal to further define "unit-based" compensation in the context of indirect compensation relationships
  - CMS also reaffirmed its antipathy toward "per-click" arrangements for space/equipment leases

Unit-Based Compensation

- 2021 final rule – attempt to create single-step analysis of indirect compensation arrangement. Indirect compensation arrangement only problematic if:
  - Unit of compensation not consistent with FMV
  - Unit of compensation varies with/takes into account volume or value of referrals
  - Unit of compensation varies with/takes into account other business generated
  - Payment for the lease/use of space/equipment
- Note: CMS views *all* compensation as "unit-based"
  - The "unit" is the smallest unit of time for which compensation is paid
  - If MD paid 50% of collections for personally performed services for a calendar year, the "unit" is the calendar year.
  - Combined service/time measures are best converted to "unit of time" for purposes of analysis
  - Beware of "tiered" compensation arrangements

COVID-19 and Stark

- COVID-19 Vaccinations/Treatment
  - Original COVID-19 vaccinations not currently payable by Medicare (paid by federal government generally) so not DHS
  - If Medicare assumes payment responsibility – vaccines qualify as DHS.
  - Exception for vaccinations (411.355(h)) is available even if no CMS-mandated frequency limit. Also applies to monoclonal antibody treatment (as long as paid under vaccine benefit).

What Comes Next?

- It may have been a while (for good reason) since the last time you reviewed your organization's Stark/AKS compliance:
  - Regulatory changes are always a good time for compliance review
  - Consider whether the new rules or clarifications shed light on existing arrangements
    - Are certain arrangements lower risk now?
    - Do we need to restructure anything?
    - Can we take advantage of new flexibility?
  - Beware of common pitfalls
    - Legacy arrangements – particularly those with automatic processes
    - Arrangements without clear purpose
    - Effective date of new flexibility or restrictions
  - What if I find something?
    - Are we covered by any of the temporary COVID flexibilities?
    - Is there a way to remedy the potential non-compliance (esp. with new flexibility)?
    - How can we unwind the potentially non-compliant arrangement?
    - Should we self-disclose?

Questions?

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