

Kickback & Stark Law Developments

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Panel

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Topics

- Stark Law Developments
 - Introduction to the Stark Law & the Stark 2016 Amendments
 - Stark Case Law Developments: U.S. *ex rel.* Emanuele v. Medicor Associates
 - Stark Reform Developments
 - Stark & Current Physician Compensation Issues
 - Physician Compensation and Mid-level Supervision and Productivity
 - Commercial Reasonableness & Physician Practice “Losses”
 - The New Self-Referral Disclosure Protocol Form
- Federal Anti-Kickback Statute Developments
 - Introduction to the Federal Anti-Kickback Statute (AKS)
 - AKS and the Employment Safe Harbor
 - AKS and Discounts
 - Recent Developments in OIG Guidance

3

Introduction to the Stark Law

- Goal of Stark Law: Prevent financial relationships from corrupting physician judgment
- Approach of Stark law: “Strict Liability”
 - Physician is prohibited from referring Medicare patients for “designated health services” to an entity if physician has a “financial relationship” with the entity, unless an exception applies.
 - Entity is prohibited from billing for designated health services provided pursuant to prohibited referral.

4

New Stark Regulations: Key Changes (October 30, 2015)

- *Leniency on “written agreement” and “one-year term” requirements*
- New exception for recruitment of mid-level clinicians
- New exception for timeshare arrangements
- Extensions on permitted “holdover” arrangements
- More latitude on missing signatures

5

How the Stark Rules Have Changed – Written Agreement/Term

- Depending on the facts and circumstances, a collection of documents, e.g., e-mails, drafts, invoices, cancelled checks, timesheets, etc. can constitute a “written agreement”
- The “one-year term” requirement can be satisfied if the arrangement lasted one year, even if the written agreement does not specify a term
- These are both “clarifications” of existing law, meaning that they apply retroactively too

6

How the Stark Rules Have Changed – Recruiting Mid-Levels

- Previously, there was just a “physician” recruitment exception
- Now, hospitals (and FQHC/RHC) can recruit mid-levels to provide primary care or mental health services to a physician’s practice
- Covers PAs, NPs, clinical nurse, specialists, certified nurse, midwives, LCSWs and psychologists
- Up to 50% of compensation, once every 3 years (and other restrictions apply)
- What about 501(c)(3) hospitals?
- Effective as of January 1, 2016

7

How the Stark Rules Have Changed – Timeshare Arrangements

- Protects certain “timeshare” arrangements (not leases, which are subject to a different exception) between hospital or physician organization and a physician or medical group
- Space, equipment and other items are predominantly for evaluation and management (E/M) visits
- Any equipment is in the same building as E/M visits and used for diagnostic imaging only if incidental to E/M visit, and not used advanced imaging, radiation therapy or clinical laboratory services (other than CLIA-waived tests)
- Could this be used in hospital-licensed or provider-based space?
- Effective as of January 1, 2016

8

How the Stark Rules Have Changed – Holdovers

- The old rule allowed expired leases and personal services arrangements to continue after expiration on the same terms for up to 6 months, if exception otherwise satisfied
- Their new rule extends the 6 months to an unlimited period of time
- But, beware of fair market value issues and changes in services and/or compensation
- Effective as of January 1, 2016

9

How the Stark Rules Have Changed – Signatures

- The old rule allowed arrangements where only a signature was missing, for up to 90 days if inadvertent and 30 days if advertent
- Now, all arrangements are allowed, when only a signature is missing, for up to 90 days
- This grace period is still limited to once per physician every 3 years
- Effective as of January 1, 2016

10

Stark Case Law Developments:
U.S. *ex rel.* Emanuele v. Medicor Associates
(W.D. Pa. March 15, 2017)

11

U.S. *ex rel.* Tullio Emanuele v.
Medicor Associates, *et al.*

- Broad Legal Context - The False Claims Act imposes liability for:
 - Knowingly submitting or causing someone else to present a false or fraudulent claim to the federal government
 - Knowingly making, using, or causing someone else to make or use a false record or statement material to a false or fraudulent claim
 - “Knowingly” means having actual knowledge of the falsity of the information, or acting with reckless disregard or deliberate ignorance of the truth or falsity of the information
 - “Materiality” means “having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property”

12

U.S. *ex rel.* Tullio Emanuele v. Medicor Associates, *et al.*

- Broad Legal Context
 - Because the Stark Law is a Medicare payment rule, hospitals can be found liable under the federal civil False Claims Act if the U.S. or relator (whistle-blower) proves:
 - The hospital submitted claims to Medicare for DHS pursuant to referrals by a physician with which the hospital has a financial relationship
 - The hospital submitted these Medicare claims when it knew or should have known that its financial relationship with the referring physician, or the physician's referrals, did not satisfy a Stark Law exception
 - The hospital's express or "implied" certification of compliance with the Stark Law was false and "material" to Medicare's decision to pay these claims

13

U.S. *ex rel.* Tullio Emanuele v. Medicor Associates, *et al.*

- Procedural Context
 - Emanuele alleged that eight medical director arrangements between The Hamot Medical Center of the City of Erie ("Hamot") and Medicor Associate, a cardiology practice
 - violated the Stark Law and the federal anti-kickback statute
 - Hamot knew or should have known of the violations
 - Hamot's claims to federal programs were "false or fraudulent" under the federal civil False Claims Act

14

U.S. *ex rel.* Tullio Emanuele v. Medicor Associates, *et al.*

- Procedural Context
 - Emanuele filed a motion for the court to enter a summary judgment that:
 - Hamot’s compensation arrangements with Medicor created a financial relationship between Hamot and Medicor’s four physician-shareholders (the “Physicians”)
 - The compensation arrangements failed the signed writing requirement of applicable Stark Law exceptions
 - Hamot filed a motion for summary judgment on the “materiality” and “scienter” (knowledge) issues, claiming
 - Its certification of compliance with the Stark signing writing requirements was not material to payment
 - It did not “knowingly” violate the Stark Law

15

U.S. *ex rel.* Tullio Emanuele v. Medicor Associates, *et al.*

- Import of the Case
 - First time a whistle-blower (relator) has brought a motion for summary judgment on the Stark Law compliance issue in an FCA case based exclusively on a failure of the hospital defendant to satisfy the Stark Law’s signed writing requirements

16

U.S. *ex rel.* Tullio Emanuele v. Medicor Associates, *et al.*

- Import of the Case (cont'd)
 - First time since the Supreme Court's decision in *Universal Health Services v. Escobar* that a court has considered whether a false certification of compliance with the Stark Law's signed writing requirements is material to the Medicare program's payment decision

17

U.S. *ex rel.* Tullio Emanuele v. Medicor Associates, *et al.*

- Signed Writing Issue
 - Court stated that satisfaction of the signed writing element of the personal services and fair market value exceptions requires that "documents outline, at a minimum, identifiable services, a time frame and a rate of compensation" (citing the fair market value exception)
 - Court ruled that there was a signed writing for six of the eight compensation arrangements, applying CMS's "collection of documents" interpretation of the signed writing requirement
 - Court relied on signed but expired contracts, back-dated addenda to the contracts, invoices and checks

18

U.S. *ex rel.* Tullio Emanuele v. Medicor Associates, *et al.*

- Signed Writing Issue (cont'd)
 - Court ruled that two of the eight compensation arrangements at issue failed the signed writing requirement of the applicable exceptions (creating a 21 month period of non-compliance)
 - Hamot produced memoranda, letters, emails, bylaws, meeting minutes, a manual, and an unsigned draft agreement
 - Applying CMS's "collection of documents" interpretation, the court ruled that the collection of documents produced were inadequate, lacking signatures and documentation of
 - identifiable services
 - a time frame; and
 - rate of compensation
 - Note: The personal services exception does not require a stated time frame and, arguably, does not require a stated rate of compensation

19

U.S. *ex rel.* Tullio Emanuele v. Medicor Associates, *et al.*

- Signed Writing Issue (cont'd)
 - The Stark isolated transaction exception does not have a signed writing requirement
 - Court rejected Hamot's argument that the isolated transaction exception applied to a December 2008 payment for medico-administrative services performed over the prior 6 months
 - Court ruled that the exception is unavailable for a payment that is an "installment in a series of payments relating to" ongoing work

20

U.S. *ex rel.* Tullio Emanuele v. Medicor Associates, *et al.*

- Materiality Issue - Background
 - The Stark Law does not have a “materiality” standard; no CMS guidance or case law supporting the notion that a failure to satisfy the signed writing requirement is not material to compliance with the Stark Law
 - The False Claims Act has a “materiality” requirement; the false or misleading statement must be material to the government’s payment decision

21

U.S. *ex rel.* Tullio Emanuele v. Medicor Associates, *et al.*

- Materiality Issue - Background
 - In *Universal Health Services v. Escobar*, the U.S. Supreme Court held that a misrepresentation of compliance with a particular law cannot be deemed material merely because the Government makes such compliance a condition of payment, or noncompliance would be grounds for denial of payment if the Government knew of the noncompliance
 - Materiality cannot be found where noncompliance is “minor or insubstantial”

22

U.S. *ex rel.* Tullio Emanuele v. Medicor Associates, *et al.*

- Materiality Issue – Court’s Decision
 - The court ruled that Hamot’s misrepresentation of compliance with the signed writing requirement of the Stark Law was material to the Medicare program’s payment decision
 - Court’s reasons:
 - Stark Law expressly prohibits payment of claims for DHS that do not satisfy the law’s requirements, including the signed writing requirement
 - Failure to satisfy the signed writing requirement is not “minor or insubstantial”
 - Evidence that CMS has imposed penalties for similar lapses in compliance (a reference to CMS’s Self-Referral Disclosure Protocol)

23

U.S. *ex rel.* Tullio Emanuele v. Medicor Associates, *et al.*

- Materiality Issue – DOJ’s Statement of Interest
 - Compliance with the Stark Law is material to Medicare’s payment decision because:
 - Stark Law compliance not merely labeled a “condition of payment” but is a mandatory condition of payment; the law expressly requires a refund of Medicare payments prohibited by the law
 - The signed writing requirement is not “minor or insubstantial” – “Compliance with the ‘writing’ requirement is critical because it ‘permit[s] a reasonable person to verify that the [financial] arrangement [at issue] complied with an applicable exception at the time a referral [was] made.’” (Quoting CMS)

24

U.S. *ex rel.* Tullio Emanuele v. Medicor Associates, *et al.*

- Materiality Issue – Comments
 - No good argument that noncompliance with the Stark Law is not material to CMS’s payment decision
 - No good argument that noncompliance with the signed writing requirement of an applicable exception is not material to compliance with the Stark Law

25

U.S. *ex rel.* Tullio Emanuele v. Medicor Associates, *et al.*

- Materiality Issue – Comments
 - There is a reasonable argument that noncompliance with the signed writing requirement of the Stark Law is not material to CMS’s payment decision
 - CMS is compromising “technical” violations like signed writing failures for pennies on the dollar, evidencing that CMS considers the violations “garden-variety” and relatively minor
 - Supreme Court in *Escobar*: “We emphasize . . . that the False Claims Act is not a means of imposing treble damages and other penalties for insignificant regulatory or contractual violations.”
 - Note: Both CMS and OIG have remedies for signed writing violations; the Government does not need draconian False Claims Act liability to protect its interest in compliance with the Stark signed writing requirement

26

Stark Reform & Legislative Developments

27

Stark Law Modernization Act of 2017

- Codifies changes CMS made to Stark Law regulations relating to when leases are in violation of the Stark Law and when signatures were required to document the terms of legal arrangements.
- Establishes general statutory authority within the Department of Health and Human Services (HHS) to recognize APMs as an opportunity to decrease costs while maintaining or improving quality.
- Creates an exemption from the physician self-referral prohibition and a safe harbor from Anti-Kickback Statute for incentive payments made by a hospital to a physician under an incentive payment program.
- Establishes an exemption from the prohibition against certain physician referrals and other compensation for any incentive payments that are made under an incentive payment program.
- Exempts incentive payments from certain civil monetary penalties and criminal penalties for illegal remunerations.
- Allows health care provider organizations participating in incentive payment programs to use their own money to help assigned patients afford primary care services necessary to manage the individual's chronic conditions.
- Creates a safe harbor for medical device manufacturers to provide remuneration pursuant to a value-based price adjustment or value-based warranty remedy.

28

Stark Administrative Simplification Act of 2017

- Originally offered by Mr. Marchant
- In mark up, Chairman Brady offered a substitute
- Bill would
 - set up an alternative process for certain providers to self-report and resolve in a timely manner tech and inadvertent violations of stark law.
 - allow these providers to pay a CMP depending upon the violation and the timeframe in which that violation was reported in order to resolve it.
 - HR 3726 requires the Sec of HHS to make a determination to accept or reject on such a disclosure within 180 days.

29

Stark Legislative Developments

- 2015 Sen. Finance Roundtable & White Paper
- Recent W & M and E & C Stark-a-thon (8/24)
- W & M Medicare Red Tape Relief Initiative
- Meehan Bill
- CMS relief?
- Stay tuned

30

Stark & Current Physician Compensation Issues

31

Physician Compensation and Mid-Levels

- Employed physician wants credit for mid-levels she manages
- Mid-levels do not provide any DHS
- Hospital wants to encourage physicians to better utilize mid-levels
- Can the physician get credit for mid-level wRVUs?

32

Physician Comp and Mid-Levels

CMS says in Phase II at 69 Fed Reg 16088:

Comment: Two commenters asked whether the employment exception would be satisfied if an employer paid an employed physician a flat fee for each mid-level provider he or she supervises in order to compensate the physician for the time spent on supervision.

Response: We see nothing in the exception that would bar flat fee compensation based on the number of mid-level providers under the physician's supervision, as long as the compensation is fair market value for actual time dedicated to supervision services and is not determined in any manner that takes into account, directly or indirectly, the volume or value of DHS referrals generated by the physician. The burden of proving the time will be on the DHS entity.

33

Physician Comp and Mid-Levels

- Employment compensation exception has no such limit
 - Compensation for identifiable services
 - FMV
 - Not determined in a manner that takes into account v/v of referrals
- “Referrals” is defined to Medicare DHS. Employment exception does not include language “or other business generated.”
- The fact that the productivity bonus exception to the volume/value prohibition is limited to “personally performed” services underscores that other services not personally performed can be compensated.
- QED: So long as overall aggregate comp fits in FMV, physicians can get compensated for mid-levels

34

“Commercial Reasonableness”

- Rental of office space
- Rental of equipment
- Personal services
- FMV compensation
- Indirect compensation
- Isolated transactions

35

Commercial Reasonableness: CMS (1998)

“We are interpreting ‘commercially reasonable’ to mean that an arrangement appears to be a sensible, prudent business agreement, from the perspective of the particular parties involved, even in the absence of any potential referrals.”

63 Fed. Reg. 1659, 1700 (Jan. 9, 1998).

36

Commercial Reasonableness: CMS (2004)

“An arrangement will be considered ‘commercially reasonable’ in the absence of referrals if the arrangement would make commercial sense if entered into by a reasonable entity of similar type and size and a reasonable physician (or family member or group practice) of similar scope and specialty, even if there were not potential DHS [designated health services] referrals.”

69 Fed. Reg. 16054, 16093 (March 26, 2004).

37

Losses on Physician Services – OK?

- DOJ has asserted that compensation to physicians that exceeds the professional collections they generate cannot be FMV and ***cannot be commercially reasonable***:
“Given that each neurosurgeon was paid total compensation that exceeded the collections received for neurosurgical physician services, Defendants could not reasonably have concluded that the compensation arrangements in those contracts were fair market value for the neurosurgical services or were commercially reasonable.” (Halifax case)

38

Losses on Physician Services – OK? (Cont'd)

- But, there is no requirement that providing physician services must be profitable:
 - If compensation is FMV and is not adjusted for referrals, it should satisfy the Stark Law
 - Some service lines have unprofitable payor mixes or low demand
 - CMS recognizes the legitimacy of subsidizing physician compensation, e.g. in the E.D.
 - Likewise, call coverage and hospitalist services often require subsidies

39

The New Self-Referral Disclosure Protocol Form

40

Stark Self-Referral Disclosure Protocol

- Mandated by ACA, passed March 23, 2010
- Issued on September 23, 2010
- Created a Self-Disclosure Path for First Time
- Effective June 1, 2017; Updated Mandatory Form for SRDP

41

Stark Law Self-Disclosure Protocol

- Used for “Stark only” self-disclosure
- Tolls the 60-day repayment obligation, but doesn’t permit payment with the self-disclosure!
- Requires detailed submission, including:
 - facts and circumstances of violation
 - legal analysis of why it doesn’t comply
 - calculation of financial damages
 - New: Formula for calculating pervasiveness of non-compliance
- New: Requires certification of non-compliance
- What types of compromise might be available?

42

Introduction to the Anti-Kickback Statute

43

AKS: Prohibition

- Knowingly and willfully
- Solicit, receive, offer or pay
- Remuneration
- For referring, for purchasing or ordering
- For arranging for or recommending
- Services covered by Medicare/Medicaid

44

AKS: Penalties

- Felony - \$25,000 fine + 5 years in prison
- Exclusion
- Civil Money Penalties
- *False Claims Act?*

45

AKS: As Applied By The Court

“One Purpose Rule” (Greber)

46

AKS and the Employment Safe Harbor

47

AKS Safe Harbors

- Over 2 dozen AKS safe harbors
- “Safe harbors” describe financial arrangements that will not constitute remuneration for AKS purposes
 - “Remuneration does not include”
- Congress required OIG to issue safe harbors and to update them
 - “[T]he breadth of [the AKS] has created uncertainty among health care providers as to which commercial arrangements are legitimate, and which are prohibited”
 - S. Rep. No. 109, 100th Cong., 1st Sess. 27 (1987) *reprinted in* 1987 U.S.C.C.A.N. 682, 707

48

AKS Safe Harbors

- Certain safe harbors track or expand upon statutory exceptions, including an exception for payments by an employer to an employee
- Generally, the safe harbors have not been very helpful because they are too narrow and their terms too restrictive
- Except the employment safe harbor, which, at least until *Borrasi*, has been very helpful

49

Anti-Kickback Employment Safe Harbor

- “[R]emuneration” does not include any amount paid by an employer to an employee, who has [1] a bona fide employment relationship with the employer, [2] for employment in the furnishing of any item or service for which payment may be made in whole or in part under . . . Federal health care programs.”
 - The term employee has the same meaning as it does for purposes of 26 U.S.C. 3121(d)(2)
 - 42 C.F.R. § 1001.952(i) (emphasis supplied)

50

Anti-Kickback Employment Safe Harbor

- “This statutory exemption permits an employer to pay an employee in whatever manner he or she chooses for having that employee assist in the solicitation of Medicare or State health care program business.”
 - 54 Fed. Reg. 3088, 3093 (Jan. 23, 1989)

51

Anti-Kickback Employment Safe Harbor

- The prevailing view of the health legal community: so long as the health care employer and individual have a *bona fide* employment relationship, the compensation is protected *even if* the purpose (or a purpose) of the compensation is to require or induce referrals or recommendations by the employee

52

Anti-Kickback Employment Safe Harbor

- Rationale:
 - If the employment safe harbor does not protect employment compensation intended to require or induce the employee to make referrals or recommendations, it is superfluous, having no function
 - Why? If the employment compensation is not in whole or in part to require or induce referrals or recommendations it does not even implicate the AKS and there is no need for an employment safe harbor

53

Anti-Kickback Employment Safe Harbor

- Courts Supporting this View
 - *United States ex rel. Obert-Hong v. Advocate Health Care*, 211 F.Supp.2d 1045 (N.D. Ill. Jan. 30, 2002)
 - *United States and Baklid-Kunz v. Halifax Hospital Medical Center*, 2013 WL 6196562 (M.D. Fla.)
 - *Hericks v. Lincare Inc.*, 2014 WL 1225660 (E.D. Pa. Mar. 25, 2014) (in dicta)
 - *United States ex rel. Wall v. Vista Hospice Care, Inc.*, 2016 WL 3449833 (N.D. Tex. June 20, 2016)
 - *United States of America ex rel. Carrel v. AIDs Healthcare Foundation, Inc.*, Sealed Order Granting Motion for Summary Judgment (S.D. Fla. June 9, 2017) (in dicta)

54

Anti-Kickback Employment Safe Harbor

- Cases Cited to Challenge this View
 - *United States v. Starks*, 157 F.3d 833 (11th Cir. 1998)
 - *United States v. Borrasi*, 639 F.3d 774 (7th Cir. 2011)

55

Anti-Kickback Employment Safe Harbor

- The Problem - “Bad Facts Make Bad Law”
 - The alleged employment relationships in *Starks* and *Borrasi* were not *bona fide* (good faith) employment relationships
 - Shams only thinly disguising “text-book” kickback schemes
 - Seventh Circuit (*Borrasi*) and Eleventh Circuit (*Starks*) could not tolerate a construction of the employment safe harbor that would allow these defendants to “walk”
 - Courts’ Error: The courts *arguably* advanced constructions of the safe harbor that
 - eviscerated and rendered the safe harbor superfluous
 - were unnecessary to hold these defendants accountable

56

Anti-Kickback Employment Safe Harbor

- Starks (11th Circuit)
 - Court noted that: “Siegel did not at any time pay Starks and Henry for any of their time, effort, or business expenses, or for any covered Medicare service.”
 - Cited for notion that the employment safe harbor is limited to compensation for federal program covered services, thus excluding payments for referrals or recommendations for covered services
 - *E.g., United States v. Luis*, 966 F.Supp.2d 1321, 1331 (S.D. Fla. June 21, 2013)
 - Other courts read *Starks* narrowly as a decision based on the lack of a good faith employment relationship
 - Noting that some payments were made in parking lots and rest rooms
 - *E.g. United States ex rel. Wall v. Vista Hospice Care, Inc.*, 2016 WL 3449833, *23 (N.D. Tex. June 20, 2016).

57

Anti-Kickback Employment Safe Harbor

- Borrasi (7th Circuit)
 - The court held that, because “at least part of the payments to Borassi was ‘intended to induce’ him to refer patients to Rock Creek, ‘the statute was violated, even if the payments were also intended to compensate for professional services.” *Id.* at 782, quoting *United States v. Greber*, 760 F.2d 68, 72 (3d. Cir. 1985).
 - Court arguably held that the employment safe harbor does not protect employment compensation if “one purpose” of the compensation is to pay for referrals

58

Anti-Kickback Employment Safe Harbor

- Borrasi (7th Circuit) (cont'd)

- Problem:

- The employment safe harbor does not and should not have a purpose test
- If the employment safe harbor has a one purpose test, the safe harbor is eviscerated, rendered superfluous
- The court did not need a one purpose test to uphold the jury's conviction

59

Anti-Kickback Employment Safe Harbor

- Borrasi (7th Circuit) (cont'd)

- Problem (cont'd)

- In *Borrasi*, certain job tasks were arguably needed and performed, and others were made up and/or not performed with the knowledge and consent of the employer (“free money” in the words of defendant)
- Such a contrived employment relationship is not a *bona fide* one even if the employer needed and received some of the work
- Court did not need to read a “one purpose” test into the safe harbor to reach the conclusion that the safe harbor was unavailable to the defendant

60

Anti-Kickback Employment Safe Harbor

- Borrasi (7th Circuit) (cont'd)
 - What does the future hold?
 - DOJ and relators faced with an employment safe harbor defense will continue to argue defendant failed *Borrasi's* one purpose test or interpret *Starks* broadly to restrict the safe harbor to payments for Medicare-covered services and items, not referrals
 - Courts will continue to struggle with “bad facts” cases where bad actors assert the employment safe harbor as a defense
 - Courts outside the 7th Circuit, like the courts in, *Halifax*, *Vista Hospice Care* and *AIDS Healthcare Foundation*, have rejected *Borrasi* , but *Borrasi* still a highly problematic precedent

61

AKS & Discounts

- The DOJ and courts have been misinterpreting and narrowing the discount safe harbor for years
- Originally intended and written to broadly protect discounts from the overly broad AKS statute
- Now it is small enough to drown in the bathtub

62

Disclosure Requirement for Charge Based Providers

- Statutory exception requires provider or supplier that receives a discount to properly disclose and appropriately report the discount on the cost report or claim submitted
- The government and courts have been mucking it up ever since

63

Discount Safe Harbor Round 1

- In *US v. Shaw*, 106 F. Supp 2nd 103, government argued that the seller was not protected by discount safe harbor because the seller had not disclosed the discounts to CMS.
- There was no obligation for sellers to disclose discounts and no way for CMS to process such information.
- The safe harbor clearly only requires the buyer submitting the claim to Medicare to disclose
- The court did reject govt's contention that disclosure needed to cover all material terms.

64

Discount Safe Harbor Round 2

- In 1999, OIG revised the discount safe harbor for charge based providers to clarify that only buyers submitting claims had to disclose the discounts to CMS and only then if CMS requested the information
 - Only disclosure required is whatever disclosure CMS requires by regulation
 - No disclosure required for charge-based providers

65

Discount Safe Harbor Round 3

- Relators are now pursuing declined cases alleging that market share discounts violate AKS and do not qualify for the discount safe harbor
- United States ex rel. Richard Templin and James Banigan et al v. Organon USA Inc. et al., 1:07-cv-12153(Dt. MA)
 - Judge denied Omnicare motion for summary judgment
 - Court held that discount safe harbor for charge based providers was only available IF THE GOVT HAD ACTUALLY ASKED FOR DISCOUNT INFORMATION AND BUYER HAD PROVIDED IT

66

Discount Safe Harbor Round 4

- Organon filed for reconsideration, but case settled before a decision.
- In a related case, *US ex rel Herman v. Coloplast*, US Dt Ct MA, CA : 11-12131, the same court denied defendant's motion to dismiss relator's claims that discounts violate AKS because in part, Coloplast had not disclosed discounts to govt as required under safe harbor (Dkt. 181)
- Court on motion for reconsideration struck language appearing to require affirmative disclosure.(Dkt. 236)
- No explanation (or maybe mea culpa?)

67

Recent Developments in OIG Guidance

- New and revised safe harbors in MMA and ACA
- New exceptions to Beneficiary Inducement CMP
- Advisory Opinions
- Judicial Deference to OIG Guidance

68

MMA and ACA AKS Safe Harbors

42 CFR 1001.952

- A technical correction to the existing safe harbor for referral services;
- protection for certain cost-sharing waivers, including:
 - pharmacy waivers of cost-sharing for financially needy beneficiaries; and
 - waivers of cost-sharing for emergency ambulance services furnished by State- or municipality-owned ambulance services;
- protection for certain remuneration between Medicare Advantage (MA) organizations and federally qualified health centers (FQHCs);
- protection for discounts by manufacturers on drugs furnished to beneficiaries under the Medicare Coverage Gap Discount Program; and
- protection for free or discounted local transportation services that meet specified criteria.

69

New Exceptions to Beneficiary

Inducement CMP

- Copayment reductions for certain hospital outpatient department services;
- certain remuneration that poses a low risk of harm and promotes access to care;
- coupons, rebates, or other retailer reward programs that meet specified requirements;
- certain remuneration to financially needy individuals; and
- copayment waivers for the first fill of generic drugs.

70

Nominal Value for Beneficiary Inducement

- 42 USC § 1320a-7a(a)(5) prohibits persons from offering or giving M/M beneficiaries remuneration likely to influence their choice of providers
- 2000 Guidance provided that individual gifts of less than \$10 per item or aggregate of \$50 annually were ok
- New guidance is \$15 per item or \$75 annually
 - <https://oig.hhs.gov/fraud/docs/alertsandbulletins/OIG-Policy-Statement-Gifts-of-Nominal-Value.pdf>

71

Recent Advisory Opinions

- Noticeable slowdown in opinions
 - Only 5 in 2017
 - Typically over 20 per year
 - Topics relatively narrow
- Biggest news is probably the DOJ investigation into Pharma Patient Assistance Plans approved by OIG

72

OIG Guidance in the Courts

- Advisory opinions, fraud alerts, bulletins are sub-regulatory guidance
- Not entitled to deference by the courts
- Only as good as the reasoning behind them
- With increasing FCA cases based on AKS violations, more courts are being called on to evaluate OIG guidance

73

US ex rel Fl. Society of Anesthesiologists v. Choudhry

M.D. FL FL Case 8:13-cv-2603 (6/14/2017)

- Anesthesiology Society brought qui tam against ASCs alleging “company model” providing anesthesiology services to ASCs violated AKS
- Relied heavily on OIG Advisory Opinion 12-06

74

Court Dismissed Complaint

To the extent Relator argues that the "company model" itself qualifies as a violation of the Anti-Kickback Statute by virtue of the OIG's Advisory Opinion No. 12-06, Relator provides no authority for that conclusion. . . Moreover, the opinion expressly stated that it "has no applicability to other arrangements, even those which appear similar in nature or scope," and the OIG concluded only that the facts "*could potentially* generate prohibited remuneration under the anti-kickback statute."

Emphasis in original. Citations omitted.

75

Latest In Long Line

- Advisory Opinions are not entitled to judicial deference
 - US ex rel McDonough v. Symphony Diagnostic, 36 F. Supp 3d 773 (2014)
 - Hericks v. Lincare, E.D. PA, Civil Action No. 07-387 (3/25/2014)
- Fraud Alerts & Bulletin
 - US ex rel Jamison v. McKesson, 784 F.Supp.2d 664 (2011)
 - HHS Dept. Appeals Board Decision No. 1275, 1991 WL at *23-24 (Sept. 18, 1991).

76

Thank you!

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