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Anti-Kickback Statute and Stark Law Compliance in Managed Care Contracts

Navigating Safe Harbors and Physician Incentive Plan Rules, Limiting Civil Monetary Penalty Exposure

WEDNESDAY, OCTOBER 23, 2019

1pm Eastern | 12pm Central | 11am Mountain | 10am Pacific

Today's faculty features:

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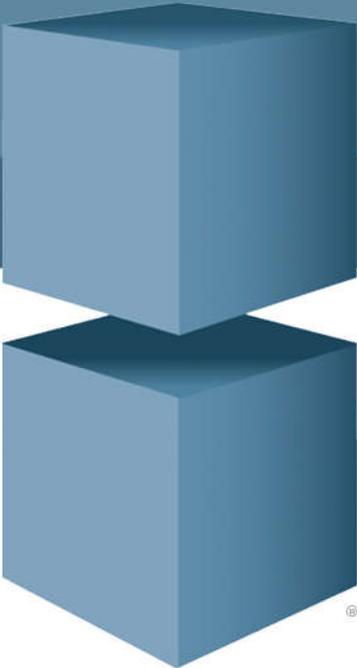
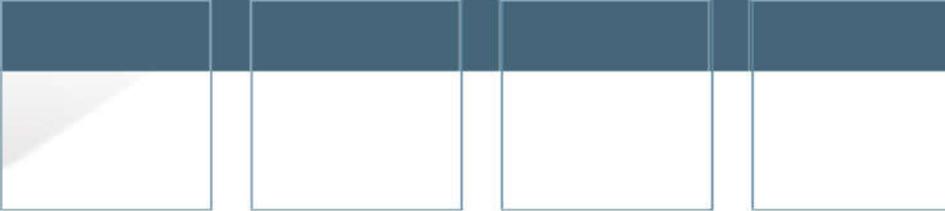
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Anti-Kickback Statute and Stark Law
Compliance in Managed Care

Contracts:

A Focus on the AKS Safe Harbors, Stark
Exceptions, and the PIP Rule



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The Managed Care World

- Given impetus by State and Federal programs, in particular the Next Gen ACO/MSSP program and state demonstration projects such as the MA Medicaid ACO Model.
- Embraced by some states and CMS which have created bundled payments, tiered networks, and other “alternative payment methodologies”
- Pushed along by value based care models being pushed through in the commercial space.

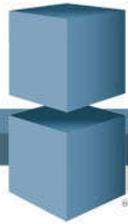




The Current State of Play

- HHS's Regulatory Sprint to Coordinated Care
- The Safe Harbors and Exceptions we discuss today stay in place





Managed Care Structures

- Its own alphabet soup – HMO, PCCM, Coordinated Care Plans (MA Plans), IDS, IPAs, PPOs, etc.
- But for analysis purposes, “follow the money” –
 - The Plan (Or the employer, ERISA Plan, Plan Sponsor, etc).
 - The First Tier Contractors
 - Second Tier Contractors
 - Downstream Contractors

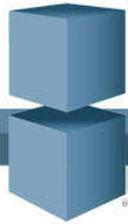




What's an MCO?

- It is not defined, but it really is any entity in the chain of payments to physicians by an entity downstream from the plan
- CMS commentary: “The new exception [at 411.357(n)] is meant to cover all risk-sharing compensation paid to physicians by an entity downstream of any type of health plan, insurance company, HMO or...IPA provided the arrangement relates to enrollees and meets the conditions set forth in the exception. All downstream entities are included. We purposefully decline to define [an MCO] so as to create a broad exception with maximum flexibility.” 69 Fed. Reg., at 16114.
- Note: It will not cover funds contributed to set up an IPA, PHO, to fund infrastructure.





First and Second Tiers

- First Tier Arrangements
 - A first tier contractor means an individual or entity that has a contract directly with a plan or other “eligible managed care organization” to provide for or arrange for items or services
- Second Tier or Downstream Arrangements
 - Arrangements between the first tier contractor and those “downstream” or at the same level, i.e. where both organizations have a contract with the first tier entity
 - More specifically, a downstream contractor “means an individual or entity that has a subcontract directly or indirectly with a first tier contractor for items or services that are covered by the first tier contract”





Managed Care Payment Relationships; A Focus on Hospital – Physician Arrangements

- The variety we see—
 - Risk share (“gain share”) payments between a hospital and physicians who refer Medicare business, or between a Plan and physicians based on hospital costs
 - Discounts offered to a risk bearing IPA by a hospital
 - Volume guaranty discount arrangements
 - Discounts offered to a hospital by physicians who want to be in the hospital’s network for managed care contracting purposes
 - Hospitals and physicians who divide funds from a “bundled payment”
 - Subcapitation arrangements between a provider (e.g. a hospital) and another type of provider (e.g. orthopedic surgeons)
 - And other arrangements, which may include P4P and quality bonus arrangements or thresholds thrown in



A key question for analysis

- What kind of Plan is at the top of the food chain?
 - This will determine the applicability of AKS safe harbors, the Stark exception, the SFR exception
- There are many plans, and in applying the various potential safe harbors, or exceptions, the greatest opportunity for flexibility occurs when the plan is a risk based plan such as a Medicare Advantage (MA) plan, a competitive medical plan (CMP), a prepaid health plan or another type of plan that operates under a risk based contract with CMS or a State health care program
- Initially for our purposes, we will assume that the Plan is a MA plan



The Analysis Begins: The Anti-Kickback Statute



- SSA Section 1128B – Criminal penalties (42 USC 1320a-7b)
 - “Knowingly and willfully solicits or receives ...any kickback ...or rebate...directly or indirectly...”
 - “...in return for referring...for the furnishing or arranging for the furnishing any item or service for which payment may be made...”
 - “...in return for purchasing, leasing, ordering or arranging for or recommending ...any good, facility service or item...”
 - “...for which payment may be made in whole or in part under a Federal health care program...”





The AKS Managed Care Safe Harbors

- 42 CFR 1001.952 [“952”][All regulatory references are to 42 CFR 1001.952 unless otherwise noted] – A statement of what is NOT remuneration for purposes of Section 1128B (42 USC 1320 a-7(b))
- Discounts – 952(h) and 42 USC 1320a-7(b)(b)(3)(A)
- Increased coverage, reduced cost sharing amounts or reduced premium amounts offered by health plans – 952(l)
- Price reductions offered to health plans – 952(m)





AKS Managed Care Safe Harbors, cont.

- Price reductions offered to eligible managed care organizations (“EMCOs”) – 952(t)
- Price reductions offered by contractors with substantial financial risk (“SFR”) to managed care organizations – 952(u)





The most flexible safe harbor – The EMCO safe harbor – 952(t)

- The Eligible Managed Care Organization (EMCO) is the most flexible (42 CFR 1001.952(t))
- Remuneration does NOT include any payments between an EMCO and a first tier contractor for “items or services” if three standards are met
 - (1) A signed written agreement, for at least a year, specifies the covered items and services, and no other claims to a federal health care program from the first tier contractor





Conditions for EMCO first tier payments

- (2) No swapping
 - (3) No shifting of costs to claim increased payments from a Federal health care program
-
- Items or services are: Health care items, devices, supplies or services OR those services reasonably related to the provision of such, including non-emergency transportation, patient education, social services (e.g. case management), UR, QA, but not marketing or pre-enrollment activities
 - Thus, if part of the payment package includes any item or service listed, it will not be construed as a payment to induce referrals from the plan (e.g. we will provide non-emergency transportation to plan enrollees, free obesity education, take home supplies), it will not run afoul of the AKS
 - If the arrangement includes a marketing component, it would not be within the safe harbor

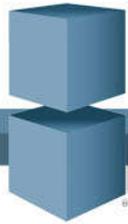




EMCOs

- EMCOs are—
 - Any Medicare Part C health plan that receives a capitated payment and which has its cost sharing approved by CMS
 - Medicaid managed care organizations
 - PACE plans or Federally qualified HMOs





This means...

- Any payment arrangement between a provider and an MA plan directly, provided it is in writing, for a least a year, etc. is not a violation of the AKS.
- This includes discounts, payments based on network configuration, payments based on volume, payments that vary over time, payments that are based on quality, all of which are a part of the payments made for the provision of “items or services” will not constitute prohibited remuneration under the AKS





And furthermore....

- The payments from the EMCO do not have to be to a provider---
"Any first tier contractor for providing or arranging for items or services..."
- The payments can be to a TPA, a management company or any other entity that is in the business of arranging for the provision of items or services—provided they are licensed to accept the payments
- Suggestion: To take best advantage of the EMCO exception— at a first tier level, have the plan rep and warrant that it is a qualifying EMCO and the payments it makes fall within the EMCO safe harbor; at a downstream level, similar reps and warranties from the first tier contractor
- If other than MA plan business is involved (e.g. Medicaid) review the law of the applicable state as well, as the exception will not supercede State law for non-Federal plan activities

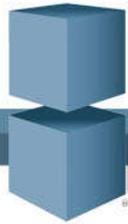


At the second tier and downstream levels....



- Remuneration does not include ANY PAYMENT between a first tier contractor and a downstream contractor (e.g. from an IPA to a hospital or the reverse) or between two downstream contractors to provide OR arrange for items or services so long as:
 - A signed written agreement, for at least a year, specifying the covered items and services, and no claim on another program
 - No swapping
 - No shift of financial burden





Downstream continued...

- Condition 4: The EMCO—First Tier Agreement does not involve
 - A cost based FQHC, HMO or CMP on a cost basis, or non-risk based Federally qualified HMO
- Downstream includes those with direct or indirectly with a first tier contractor (an individual or entity). This will include anyone in the arrangement, including suppliers, ancillary providers, independent contractors with contracts with an entity that itself has a contract with the first tier contractor to provider or arrange for provision of items or services





Downstream flexibility as well

- ANY PAYMENT is again covered
- As long as it is for items or services that are covered in the first tier arrangement
- Suggestion: Downstream contractors should verify that the services are covered by the First Tier contract. A first tier contract that carves out specialty services, high cost drugs, vision services will not protect hospital-physician arrangements downstream that involve the provision of those services (e.g. collateral arrangements)



Recommended Contractual Protections



- EMCO/First Tier representation and warranty
- No swapping language
- Language specifying that provider cannot claim payment in any form directly or indirectly from a Federal health care program for items or services covered under the agreement



Price reductions offered to health plans

-952(m)



- Remuneration does not include a reduction in price a contract health care provider offers to a health plan in accordance with a written agreement for “the sole purpose of furnishing to enrollees items or services” which are covered by the Plan
- Term not less than a year, items and services specified in advance,
- Methodology specified in advance





Examples

- A 10% discount from billed charges for a one year period for covered services provided by the hospital—Covered
- A 10% discount from billed charges for a one year period for bundled services from a hospital with downstream contract with the physicians—Not covered
- A 10% discount based on anticipated volume, which, if volume is not met within 3 months of the effective date, goes to 5% – Covered
- Anticipated volume does not appear as the parties expected, and the parties agree to terminate the arrangement prematurely and enter into a new contract with different terms and conditions? Covered if no other factors at work? Likely not. AKS violation?





The Discount Safe Harbor

- Discounts – 952(h)
 - Remuneration does not include a discount that meets the reporting obligations of the safe harbor
 - A MA plan need not report the discount unless specifically required by its contract
 - Must be applicable to Medicare, Medicaid or other Federal health care programs
 - Cannot be in cash
 - Cannot be part of a “swapping” arrangement
 - Cannot consist of a waiver of a co-pay, coinsurance or deductible

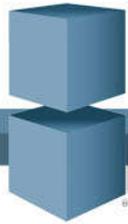




Price reductions by contractors with SFR to MCOs – 952(u)

- More challenging than the EMCO safe harbor and, in some cases redundant
- First tier application to – A qualified managed care plan if 5 standards are met
 - An agreement which is for at least a year, signed by the parties, requiring QA program and specifies a methodology that is “commercially reasonable and consistent with [fmv]





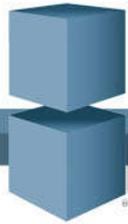
SFR Contractor safe harbor cont.

- If 1st tier contractor has an investment interest, cannot be a kickback (circular criteria?)
- First tier contractor must have substantial financial risk (capitation, % of premium, DRG payments, bonus/withhold program [20/10 requirement on target payments], reasonable payments amounts resulting, etc., etc.
- Reimbursable items or services must be submitted directly to the Federal program in accordance with a valid assignment and payments must be “identical to payment arrangements...[related to] other beneficiaries” for same items or services

AND

- No swapping or shifting the financial burden





For downstream contracts...

- Must still be substantial financial risk at the downstream level [952(u)(ii)]
- Payment arrangements must also involve a valid reassignment and identical reimbursement for same items or services
- No swapping or burden shifting





A qualified managed care plan is...

- Operates in accordance with a contract, agreement or statutory demo authority approved by CMS or a State health care program
- Charges a premium and its premium structure is regulated by the State
- Is an employer, or welfare fund; OR
- Is licensed in the State, contracts with an employer, union welfare fund or company furnishing coverage and is paid a fee for administration of the plan which is at FMV
- AND – Runs UR/QA programs and “treatment for Federal ...beneficiaries ..is not different...”
- AND – Has population that matches up to Medicare beneficiary limits (10%/50%)





Increased coverage, reduced cost sharing, or reduced premiums – 952(I)

- Applies to a plan that offers additional coverage of any item or service, or a reduction of the member obligation (e.g. copay or deductible) or a reduction in premium amounts attributable to items or services covered by the Plan, Medicare program or a State health care program
- Plan definition is specific (952(I)(2))
- Must fall within two categories of plan

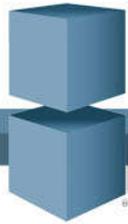




Increased coverage, etc...

- Risk based plans –
 - Must offer same increase coverage, reduced cost-sharing or premium amounts to all Medicare or State plan enrollees (absent approval)
- Cost based plans –
 - Same coverage etc. required
 - May not claim costs as bad debt or otherwise shift the burden





The Stark Law

- Physician may not refer:
 - Medicare patients
 - for “designated health services”
 - to an entity with which the physician *or*
 - an immediate family member has
 - a “financial relationship”
- ...unless the arrangement satisfies the requirements of an applicable exception





Stark – Does it even apply?

- The Stark Law is implicated where there is a referral by a physician to an “entity” with which the physician (or immediate family member) has a financial arrangement
- “Entity” is defined at §411.351 as excluding “a health care delivery system that is a health plan (as defined at §1001.952(l) of this title), and other than any managed care organization (MCO), provider-sponsored organization (PSO), or independent practice association (IPA) with which a health plan contracts for services provided to plan enrollees)”
 - Does include a health plan, MCO, PSO, or IPA that employs a supplier or operates a facility that could accept reassignment from a supplier with respect to any DHS provided by that supplier





Compensation exception for Risk Sharing Arrangements (411.357(n))

- Compensation pursuant to a risk sharing arrangement between an MCO or an IPA and a physician (either directly or indirectly through a contractor) for services provided to enrollees of a health plan (MA plan for example) does NOT constitute a financial arrangement for Stark purposes
- The conditions
 - Cannot be a violation of the AKS
 - Cannot violate a law governing billing or claims submission

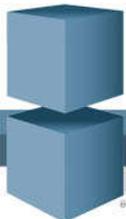




What does this mean?

- There are no limitations in the regulations other than it must be for services provided to enrollees, and does not extend to supplies (bundles may not be included!)
- Any type of compensation arrangement between and MCO or an IPA is covered
- The normal Stark requirements will not apply—
FMV, written agreement requirements simply do NOT apply





And a service-based Stark Exception (411.355(c))

- The prohibition on referrals does not apply to services furnished by an organization (or its contractors or subcontractors) to enrollees of specified prepaid plans
- The plans are – MA plans, a demonstration project which pays any organization on a prepaid basis, other health care prepayment plans with CMS agreements
- Does not extend to services provided to enrollees of any other plan or line of business which may be offered





The scope of the exception

- The prohibition on referrals is removed as the result of referrals between or among first tier, second tier or downstream providers as long as the referrals related to the provision of services to a qualifying plan
- The existence of a risk sharing arrangement is not required for the prohibition on referrals to be removed
 - Physicians can make referrals to hospitals without those referrals being subject to the Stark rules as long as the patients are MA plan enrollees





The Stark Conclusion

- If an MA capitated plan is involved, there will be no Stark prohibition on referrals or payments between participating hospitals, labs, ASCs and physicians who may hold a financial interest with those entities
- This means that Stark requirements such as FMV in the financial relationships among those participating in the provision of services to enrollees of a MA plan need not be considered
- Thus, from a Stark perspective, the allocation of a risk pool or the sharing of a “gain share” arising from hospital and physician participation will not be constrained by Stark
- But—consideration must still be given to other potential issues arising from the AKS, PIP rules and the CMPs

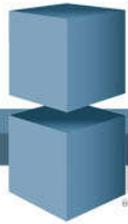


Downstream Analysis Must Be Done Separately



- CMS Demonstration Project Waivers
 - Next Gen ACO Waivers
 - BPCI Waivers
- Gainsharing Opinion
 - OIG Advisory Opinion 17-09
- Considerations outside of the Medicare Space





The proposed rules

- The proposed Stark Rule Updates
 - New Stark exception for value based activities
 - New definitions for *value-based activity, value-based arraignment, value-based enterprise, value-based purpose, VBE participation, and target patient population*

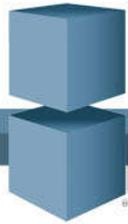




The proposed rules

- Anti-kickback Statute Updates
 - 3 new safe harbors that would protect value based arrangements
 - OIG is proposing to protect the furnishing of tools and support to patients that would improve quality, health outcomes and efficiency of services





The proposed rules

- More reporting, auditing, and compliance obligations.
- Technical definitions that need to be followed
- Certain exclusions

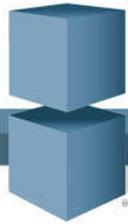


The CMP Statute Prohibitions – 42 CFR 1003.100 et. seq.



- Imposition of civil monetary penalties if a provider “substantially fails to provide...required medically necessary items and services..”
- Or on persons that “...do not meet the requirements for physician incentive plans...”
- Prohibits a hospital (or CAH) from knowingly making a payment, directly or indirectly, to a physician as an inducement to reduce or limit *medically necessary* services to a Medicare or Medicaid beneficiary who is under the direct care of the physician
 - “medically necessary” inserted by MACRA
 - Gainsharing prohibition for FFS now essentially moot given MACRA change





Example

- MCO organization pays a share of the surplus to physicians for meeting certain quality and cost containment targets. Included in the criteria is that the physicians order implantable devices from an approved list. The list of approved devices contains pacemaker devices by different manufacturers, but does not contain an implantable cardiac defibrillator
 - Likely would violate the CMP Statute
 - Likely would not meet the Stark PIP exception (may or may not meet another exception)

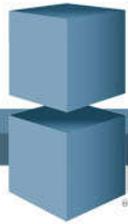




Example

- MCO organization and Hospital offer Medicare and Medicaid enrollees free movie tickets when mammograms are performed at Hospital (but not at other hospitals)
- May violate the beneficiary inducement provisions of the CMP Statute





Physician Incentive Plan Rules

- CMP Statute originally prohibited payments by both hospitals *and* Medicare managed care plans to induce physicians to reduce clinical services. It was subsequently amended to delete the reference to Medicare managed care plans
- SS Act permits MA Plans to implement physician incentive plans, provided the PIP does not induce the reduction of medically necessary care to individual patients and does not place the physician at substantial financial risk for services not provided by the physician.
 - If the plan places a physician or physician group at “substantial financial risk” for services not provided by the physician, the MA Plan must provide stop—loss protection for the physician or group that is “adequate and appropriate”
- PIP requirements apply to an MA Plan and ANY of its subcontracting arrangements that utilize a PIP in their arrangements with physicians.

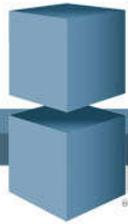




Physician Incentive Plans

- Stark Exception for PIPs
- Permits compensation determined in any manner (withhold, capitation, bonus or otherwise) that takes into account directly or indirectly Volume or Value of Referrals
 - Protects also payments made by downstream subcontractors
- Incorporates statutory requirement of no inducement to limit medically necessary services and requirements when placing physician or group at substantial financial risk (SFR)





PIP – The Definitions

- A PIP is ANY compensation arrangement to pay a physician or physician group that may DIRECTLY or INDIRECTLY have the effect of reducing or limiting the services provided to any plan enrollee
- Risk threshold means the maximum risk, if the risk is based on referral services, to which a physician or physician group may be exposed under a PIP w/o being at SFR—This is set at 25%.
- Referral services means any specialty, inpatient, outpatient, or lab services that the physicians order or arrange, but do not furnish directly
- So if physicians are at risk for specialty services, e.g. specialty surgeons, hospital costs, outpatient surgical services, lab costs that THEY order or arrange, the PIP rules will potentially have application

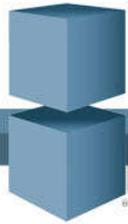




The Basic Rules

- ANY PIP operated by an MA organization must meet the following—
 - There may be no payments as an inducement to limit services to any particular enrollee
 - If the PIP puts the physicians at SFR, FOR SERVICES THAT THE PHYSICIANS DO NOT FURNISH THEMSELVES, the Plan must assure aggregated or per-patient stop loss protection
 - The MA must furnish assurances that the requirements are met
 - MA must inform beneficiaries about the arrangements





SFR – What is it?

- SFR occurs when risk is based on the use or costs of referral services and the risk exceeds the risk threshold
 - This means that where risk is based on quality targets, the amounts are not considered.
- The risk threshold is 25% of potential payments

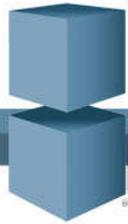




SFR– Applying the definition

- Arrangements which cause SFR (if panel size is below 25,000)
 - Withholds >25%
 - Withholds < 25% if there is also downside risk so total exposure is >25%
 - Bonuses > 33% or potential payments minus the bonus
 - Withholds + bonuses > 25% (Withhold % = $-.75(\text{Bonus \%}) + 25\%$)





Capitation for PIP determinations

- Capitation=\$payment/patient/time period without regard to the volume of services provided
 - Services may be the physicians, or referral services, or all medical services
 - Example: Payment is based on a % of premium with a sharing of a “surplus pool”. % of premium is not capitation; analysis under bonus measurement
- SFR for capitation—
Min/max differential > 25%
Min/max “not clearly explained”





Stop loss requirements

- The MA plan must ensure that the physicians who bear SFR have:
 - a. Aggregate stop loss equal to 90% of the amount by which the costs of referral services exceed 25% of potential payments; or
 - b. If on a per-patient stop loss basis, in accordance with CMS rules based on panel size

Pooling of populations (Medicare, Medicaid, commercial), subject to specific rules for pooling (422.208(g)), e.g. comparability of risks

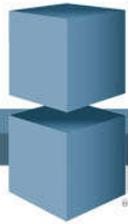




EXAMPLE 1

- Physician Practice enters into a risk/ capitation arrangement with the MA plan (and is at risk for hospital services). Hospital gives Physician Practice discount in exchange for volume guarantee
 - Discount can be protected by discount safe harbor (1001.952(h))
 - Discount can be protected by EMCO safe harbor (1001.952(t))
 - Stark does not apply to discount to group practice as Hospital is not a DHS entity in this arrangement
 - Moreover discount is excepted from being a “financial relationship” under Stark

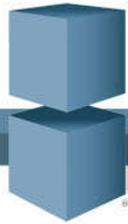




EXAMPLE 1A

- Same as 1 but discount is only on managed care business and not on FFS business
 - Swapping concerns?





EXAMPLE 1B

- Group has full risk arrangement with Plan
- Hospital gives Group Discount on FFS and agrees to share with physicians a percentage of savings
- Discount can be protected by discount safe harbor (1001.952(h), or EMCO safe harbor (1001.952(t)), or price reductions to health plans (1001.952(m))
- Payments to Physicians can comply with Stark





EXAMPLE 2

- Hospital contracts with MA Plan to give discounted rates
 - Discount can be protected by discount safe harbor (1001.952(h), or EMCO safe harbor (1001.952(t)), or price reductions to health plans (1001.952(m))
 - Stark does not apply to discount to MA Plan because no financial arrangement between hospital and physicians (and MA Plan is not DHS entity)





EXAMPLE 3

- MA Plan establishes 3 Funds, Part A, Part B and Part D,
- Plan pays Hospital and other providers on a percentage of premium basis
- Plan pays 60% of surplus to physicians, 10% to Hospital and retains the remaining 30%
- Discount, EMCO and Price Reductions to Plans Safe Harbors Potentially Applicable
- PIP payments to Physicians

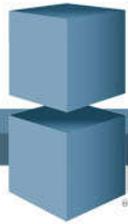




EXAMPLE 3A

- Same as 3 but Plan pays 100% of surplus to physicians
- No limit on how much Plan can pay Physicians under PIP rules





Example 4

- Plan contracts with TPA to manage physician services
- Plan pays TPA a percentage of the premiums for TPA to manage the network and Hospital enters into agreement to share with the TPA what it gets from the Plan

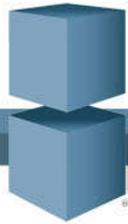




Example 5

- Hospital has contract with MA Plan and gets a share of savings in reduction of length of stay or alternatively a reduction in pharmacy costs
- Hospital pays physicians to incentivize savings





Example 6

- Hospital gives affiliated physician group a discount on services provided to capitated patients at the Hospital. Discount is paid as a rebate from the Hospital to the physician group.





Official Guidance

1. Managed Care Safe Harbors

- 54 FR 3088 (Jan. 23, 1989) – proposed safe harbor for “Discounts” (1001.952(h))
- 56 FR 35952 (Jul. 29, 1991) – final rule establishing “Discounts” safe harbor
- 57 FR 52723 (Nov. 5 1992) – Interim final rule establishing safe harbors for “Increased coverage, reduced costsharing amounts, or reduced premium amounts offered by health plans” (1001.952(l)) and “Price reductions offered to health plans” (1001.952(m))
- 59 FR 37202 (Jul. 21, 1994) – proposed clarification to “Discounts: safe harbor
- 61 FR 2122 (Jan. 21, 1996) – final rule, revising the three managed care safe harbors published in the Nov. 5, 1992 final rule
- 64 FR 63504 (Nov. 19, 1999) – safe harbors for “Price reductions offered to eligible managed care organizations” (1001.952(t)) and “Price reductions offered by contractors with substantial financial risk to managed care organizations” (1001.952(u))
- 64 FR 63518 (Nov. 19, 1999) – final rule clarifying “Discounts” safe harbor
- available at <http://oig.hhs.gov/fraud/docs/safeharborregulations/getdoc.pdf>





Official Guidance

Advisory Opinions discussing managed care safe harbors

- AO –00-04 (1001.952(t))
- AO-- 98-05 (1001.952(m))

There are no reported cases that mention 1001.952(l), (m), (t), or (u). There are no cases that discuss 1001.952(h) in the context of a managed care arrangement





Official Guidance

2. Stark – Preamble Language – Definition of “Entity”

- 66 FR 856, 912-14 (Jan. 14, 2001)
(Phase I final rule)
- 69 FR 16054 , 16067, 16082 (Mar. 26,
2004) (Phase II final rule)





Official Guidance

2. Stark – Preamble Language

411.355(c) (service based exception)

- 57 FR 8588, 8597 (Mar. 11, 1992) (proposed rule)
- 60 FR 41914, 41950-51 (Aug. 14, 1995) (final rule)
- 63 FR 1659, 1696-98, 1711-12 (Jan. 19, 1998) (proposed rule)
- 63 FR 34968, 35003-35004 (Jun. 26, 1998)(interim final rule)
- 66 FR 856, 859, 911-15 (Jan. 14, 2001) (Phase I final rule)
- 69 FR 16054, 16067, 16081-82, 16114 (Mar. 26, 2004) (Phase II final rule)
- 72 FR 51012, 51035 (Sept. 5, 2007) (Phase III final rule)





Official Guidance

2. Stark – Preamble Language --

411.357(n) (managed care exception)

- 66 FR 856, 912-14 (Jan. 14, 2001) (Phase I final rule)
- 69 FR 16054, 16067, 16082, 16114 (Mar. 26, 2004) (Phase II final rule)
- 72 FR 51012, 51060 (Sept. 5, 2007) (Phase III final rule)





Official Guidance

2. Stark – Preamble Language -- 411.357(d)(2)) (PIP exception)

- 63 FR 1659, 1669, 1712 (Jan. 19, 1998) (proposed rule)
- 69 FR 16054, 16068, 16089-91 (Mar. 26, 2004) (Phase II final rule)
- 72 FR 51012, 51046-47 (Sept. 5, 2007)

There are no reported cases that mention 411.355(c), 411.357(n) or 411.357(d)(2)



Preferred Hospital Networks and Medigap Programs



Advisory Opinion 16 – 11

- Preferred networks promoted by MediGap insurers
- Policy holders get a premium credit for the use of preferred hospitals
- Based on a shared savings program and a preferred network
- Full deductibles due for OON hospitals

