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Wave the Checkered Flag! The Stark and Anti-Kickback Rules Cross the Finish Line


Starts at 11:30 a.m.

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Wave the Checkered Flag! The Stark and Anti-Kickback Rules Cross the Finish Line



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Topics

- Modification and Clarification of Existing Concepts
- Value-Based Exceptions and Safe Harbors
- Revised and New Exceptions and Safe Harbors

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Background

- Sprint to Coordinated Care
 - Proposed rules - issued in October of 2019
 - Final rules – issued December 2, 2020
 - Effective January 19, 2021
 - Exception – Group Practice changes effective January 1, 2022

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Clarifications: The Big 3

- Fair Market Value
- Commercially Reasonable
- Volume and Value

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Clarifications: The Big 3

- Fair Market Value – What has changed?
 - Separate standards for different transactions
 - Asset acquisitions
 - Compensation arrangements
 - Leases
 - Decoupled from volume and value

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Clarifications: The Big 3

- Fair Market Value – CMS commentary most important
 - FMV is based solely on the economics of the transaction
 - Use of survey data
 - No “safe harbor” or rebuttable presumption
 - Recognized as a good start
 - Facts and circumstances matter
 - Median may not be FMV
 - Compensation above 75th percentile may be FMV

Clarifications: The Big 3

- Commercially Reasonable
 - Largely undefined (until now)
 - Still based on management decisions and thoughts BUT
 - Formal definition provides greater certainty when evaluating arrangements
 - Furthers a legitimate business purpose of the parties
 - Sensible considering the characteristics of the parties

Clarifications: The Big 3

- Commercially Reasonable
 - Profits expressly not required, however, not dispositive
 - Legitimate business purposes must still exist in the absence of referrals
 - Matters like community need and other economic consequences may be considered

Clarifications: The Big 3

- Volume and Value
 - Not definitional, but a new special rule on compensation
 - Does the compensation to (or from) the physician include referrals as a variable in the formula and result in an increase (or decrease) in compensation in a manner that positively (or negatively) correlates with referrals?

Clarifications: The Big 3

- Volume and Value
 - Physician receives compensation (e.g. professional services agreement)
 - Does compensation increase for each referral?
 - Physician pays compensation (e.g. rental arrangement)
 - Does the rental rate decrease as referrals increase?

Clarifications: The Big 3

- Volume and Value
 - wRVU-based payments do not take into account the volume and value of referrals even though DHS is often tied to the wRVU
 - Proposed rule related to circumstances where fixed compensation arrangement would take into account volume and value was not finalized

Is the Price Wrong?



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Group Practice Compensation Changes

- In-office ancillary services exception requires “group practice” in most circumstances
- Profit sharing/bonus must not *directly* be related to the volume or value of DHS
- Historically the regulations contained safe harbors that would deem a profit sharing arrangement and bonus distribution to not directly relate to the volume or value of DHS
 - Per capita
 - Based on non-DHS services
 - De minimis

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Group Practice Compensation Changes

- Changes and clarifications:
 - Continues to permit subgroups of 5 physicians BUT physicians cannot be a member of one group for one category of DHS and a member of another group for another category of DHS
 - All subgroups must be made up of at least 5 physicians
 - All DHS must be aggregated and distributed in the same manner within the same group
 - Profit sharing and bonus methodologies may only be set prospectively
 - DHS concept applies to all payors, not just Medicare payments
- Permits “profits from designated health services that are directly attributable to a physician’s participation in a value-based enterprise [...] may be distributed to the participating physician”
- Not effective until Jan. 1, 2022

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Group Practice Profits



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Modifications & Other Interesting Tidbits

- Inpatient hospital services
 - Not DHS if the service does not increase reimbursement under PPS
- Important when determining potential scope of repayment/disclosure related to a non-compliant arrangement

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A Rounding Error



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Modifications & Other Interesting Tidbits

- Isolated Financial Transactions
 - Expressly does not protect payments for services
 - Because no set in advance/writing standard, the exception was sometimes used to protect what would otherwise be a problematic services arrangement
 - Potential indirect consequence:
 - Exception was often used to settle potentially litigious matters between hospitals and physicians pursuant to an FMV settlement; proposed rule brought this into question
 - Final rule included explicit language regarding forgiveness of amount at issue in a bona fide dispute

Modifications & Other Interesting Tidbits

- Disputes
 - Isolated Financial Transaction Exception protects the settlement of the dispute itself as a new financial arrangement
 - Settlement of dispute does not bring prior financial transaction into compliance with an exception
 - The disputed arrangement must have satisfied an exception *at that time*
 - Cannot “turn back the clock” to cure what was otherwise a non-compliant relationship by entering into a settlement

Modifications & Other Interesting Tidbits

- Period of disallowance has been deleted
 - The concept remains valid, but CMS felt it was misleading and constraining
 - Did parties need to recover outstanding amounts to end the period of disallowance?
 - Claims still disallowed when a non-compliant arrangement exists, but based on facts and circumstances

Modifications & Other Interesting Tidbits

- Mistakes
 - Period of disallowance rule and commentary muddled the water
 - CMS provided a new special rule specifically addressing administrative mistakes
 - Must fix prior to terminating the arrangement but not later than 90 consecutive calendar following the end of the arrangement
 - This is not a settlement of a disputed amount
 - Deeming rule; not all payment mistakes will lead to non-compliance

Modifications & Other Interesting Tidbits

- Mistakes and Settlements – Pros and Cons
 - Certainty - Previously no black and white guidance related to administrative mistakes or settlements of disputes
 - Timeline –
 - Identification of mistake
 - Can take some time to work through the issue
 - Will the physician agree?
 - When does it become a dispute?
 - If a matter is disputed, did the underlying arrangement satisfy the “set in advance” and other standards of the applicable exception?

A Former Agreement Disagreement



Modifications & Other Interesting Tidbits

- “Set in advance” writing requirement is only a “deeming” provision
 - Collection of documents and delay concepts only applied to the writing and signature requirements
 - Can satisfy “set in advance” standard through other means
 - Applies to a new arrangement

Modifications & Other Interesting Tidbits

- Parties may *modify* compensation at any time and satisfy the “set in advance” requirement so long as:
 - All applicable elements of an exception are satisfied at the time the compensation arrangement is modified
 - The compensation is determined before the furnishing of items/services/space
 - The compensation is set forth in a writing before the furnishing of items/services/space
- Not a deeming provision; must be satisfied each time compensation is modified
- Exceptions do not require that compensation remain in place for 1 year provided that the above conditions are met; Compensation amendments may take place within 1 year

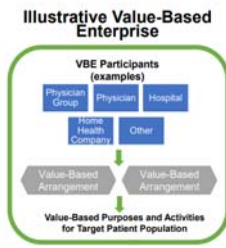
Verbal Call Arrangement



Value-Based Concepts

- Required a wholesale reconsideration of fraud and abuse laws
 - Originally created in a fee-for-service payment world
 - Terminology, incentives and abuses are different in a value-based reimbursement world
- Desired flexibility – HHS wanted to be neutral in developing exceptions and safe harbors so that the elements could apply to a wide variety of arrangements

Definitional Framework



Value-Based Baseline Elements

| Stark Exception Elements | AKS Safe Harbor Elements |
|---|---|
| Remuneration must be a result of action taken or not taken | Remuneration is connected to VB purposes and other requirements |
| Does not limit medically necessary services | Signed writing requirement (in advance for some) |
| Does not condition referrals for non-TPP | Does not take into account other referrals/business |
| Limits on requiring referrals due to patient choice, professional judgment, insurance requirements, writing requirement | Certain providers/suppliers are excluded from participation |
| Recordkeeping requirement | Recordkeeping requirement |

Full Financial Risk

- VBE is at full financial risk (or K obligated to be there within 12 months) for the entire duration of the arrangement
- No reduction in medically necessary care
- Establishes a QA program
- No claim for payment for services covered in the arrangement

Meaningful Downside Risk to a Physician Exception

- Physician is at meaningful downside risk during entire duration of arrangement
 - “meaningful downside risk” means physician is responsible to repay or forego no less than 10% of the total value of remuneration the physician receives.
- Physician’s risk (nature and extent) is set forth in writing
- Methodology used to determine amount of remuneration is set in advance of the VB activities

Substantial Downside Risk Safe Harbor

- VBE assumes substantial downside financial risk (or agrees to within 6m) from a payor for at least 1 year
- VB Participant is at risk for a meaningful share
 - Risk of 30% of any loss of total cost of care
 - Risk of 20% of any loss of defined clinical episode across more than one care setting
 - Prospective per-patient payment designed to produce material savings and paid on a set basis for defined care
- No limit on provider judgment, patient preference, payor requirements, etc.
- No inducement to limit services

Value Based Arrangement Exception Care Coordination Safe Harbor

- Changes to outcome measures are prospective
 - Remuneration methodology set in advance
- Writing requirement includes:
 - VB Activities
 - Expectation of meeting purposes
 - TPP
 - Type/ nature of remuneration
 - Determination of remuneration
 - Outcome measures
 - Monitoring requirement
 - Commercial reasonableness
 - Outcome measures are objective, measurable, clinically-based
- Remuneration is in-kind
 - Recipient pays 15% of cost of remuneration
 - Technology participant restrictions
 - No diversion of remuneration

Monitoring Requirements

- Regular monitoring
 - At least annually (or once if shorter duration)
 - Must assess specific elements of the arrangement
- Modification/correction/termination requirements if

VBE Payments



Modified Exception Highlights

- Payments by a physician
 - Compensation for items or services
 - Must be FMV
 - But, no writing requirement
 - Carve-out
 - CMS clarified that only arrangements that would be protected by a statutory exception are carved out
 - Even if FMV exception would apply, can utilize the payments by a physician exception
 - Could use for payments related to storage space (non-office space)

Payments by a Physician



Modified Exception Highlights

- Unrelated to DHS Exception
 - No writing or set in advance standard
 - Requires “completely unrelated”
 - CMS proposed relaxation of standard - not related to patient care services
 - CMS declined to adopt modified rule

Modified Exception Highlights

- EHR Items and Services
 - Scheduled to sunset on 12/31/2021
 - CMS removed sunset
 - Clarified issues related to replacement technology

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New Exception Highlights

- Limited Remuneration to a Physician
 - \$5,000 annual aggregate
- Cybersecurity and Technology Related Services
 - Nonmonetary remuneration only

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Limited Payments



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Modified Safe Harbor Highlights

- Personal Services and Management Safe Harbor
 - Now permits compensation formula (deletion of requirement of aggregate comp set in advance)
 - Outcomes-Based Payments permitted
- Warranties
- EHR Items and Services
 - Removal of sunset
- Local Transportation
 - Increased distance to 75 miles for rural patients; mileage doesn't apply to discharge of inpatient/certain observation patients

New Safe Harbor Highlights

- Patient Engagement Arrangements
 - Another Value-Based Safe Harbor
 - In-kind item or service; no cash
- CMS Sponsored Arrangements
- Cybersecurity Technology and Related Services
 - Nonmonetary remuneration only

Thank you!



Questions?

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