BH | BAIRD HOLM LLP ATTORNEYS AT LAW

Changes and Modifications to the Stark and Anti-Kickback Rules

Andy Kloeckner
akloeckner@bairdholm.com
(402) 636-8222

Agenda

- Changes to the "Big 3"
- Modifications and Clarifications
- Revised Exceptions
- New Exceptions and Safe Harbors

BH | BAIRD HOLM LLP ATTORNEYS AT LAW

2

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

BH | BAIRD HOLM LLP ATTORNEYS AT LAW

3

The Big 3

- Fair Market Value
- Commercially Reasonable
- Volume and Value

BH | BAIRD HOLM LLP ATTORNEYS AT LAW
4

Clarifications: The Big 3

- Fair Market Value – What has changed?
  - Separate standards for different transactions
    - Asset acquisitions
    - Compensation arrangements
    - Rental of Equipment or Office Space

BH | BAIRD HOLM LLP ATTORNEYS AT LAW
5

Clarifications: The Big 3

- Fair Market Value – What has changed?
  - Decoupled from volume and value, BUT
  - All consider "bona fide bargaining between well informed buyer and seller that are not in a position to generate business for each other."

BH | BAIRD HOLM LLP ATTORNEYS AT LAW
6

Clarifications: The Big 3

- Fair Market Value
  - We don't have new bright line tests or safe harbors
  - Use of survey data - Recognized as a good start, but not a safe harbor

BH | BAIRD HOLM LLP ATTORNEYS AT LAW
7

Clarifications: The Big 3

- Fair Market Value
  - Facts and circumstances matter
    - FMV is based solely on the economics of the transaction
    - Median may not be FMV
    - Compensation above 75th percentile may be FMV

BH | BAIRD HOLM LLP ATTORNEYS AT LAW
8

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

BH | BAIRD HOLM LLP ATTORNEYS AT LAW
9

Clarifications: The Big 3

- Commercially Reasonable
  - Profits expressly not required, however, not dispositive
  - Legitimate business purposes must still exist "even if there were no referrals by the physician to the employer or between the parties." (sounds like V/V)
  - Matters like community need, timely access to health care services, fulfillment of licensure or regulatory obligations, the provision of charity care, the improvement of quality and health outcomes and other economic consequences may be considered

Hypothetical – Physician Comp

- Physician recruitment where
  - On the one hand
    - Cost of living is low or reasonable
    - Good schools
    - Declining reimbursement rates
    - Hospital's financial position is tenuous
  - On the other hand
    - Aging medical staff
    - Recruitment and retention has been difficult
    - High community need

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?

BH | BAIRD HOLM LLP ATTORNEYS AT LAW
13

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

BH | BAIRD HOLM LLP ATTORNEYS AT LAW
14

Isolated Financial Transactions

- Isolated Financial Transactions
  - Does not protect payments for services
  - 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

BH | BAIRD HOLM LLP ATTORNEYS AT LAW
15

Bona Fide Disputes

- Isolated Financial Transaction Exception protects the settlement of the dispute itself as a "new" financial arrangement
- Settlement does not cure compliance issues with past transaction
  - The disputed arrangement must have satisfied an exception *at that time*
  - Cannot use the ISO exception to "turn back the clock" to cure what was otherwise a non-compliant relationship

BH | BAIRD HOLM LLP ATTORNEYS AT LAW
16

No More "Period of Disallowance"

- Well, not really…
  - Period of disallowance has been deleted
  - CMS felt it was misleading and constraining
- Claims are still disallowed when a non-compliant arrangement exists
- Scope of exposure based on facts and circumstances

BH | BAIRD HOLM LLP ATTORNEYS AT LAW
17

Mistakes

- "Period of disallowance" and related commentary muddied 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

BH | BAIRD HOLM LLP ATTORNEYS AT LAW
18

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?

Hypo—Former Agreement

- PSA with group, monthly rate with CPI increase
- PSA terminates
- Six months later, Compliance Officer discovers rate was not increased by CPI due to H acctng dept error-$100k
- Does H have to seek recovery?
- What if group says PSA is terminated, H error, and some payments over 3 years old?
- Can the parties settle for something less?

"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 as well
  - Applies to new arrangements

Modifications and "Set in Advance"

- 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

BH | BAIRD HOLM LLP ATTORNEYS AT LAW
22

Modifications and "Set in Advance"

- 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

BH | BAIRD HOLM LLP ATTORNEYS AT LAW
23

Hypo—Verbal Call

- Handshake agreement with new physician to pay $150 per hour for call
- Compliance officer finds out and says the agreement must be in writing, so the parties sign an agreement on the 60th day
- What if they decide at day 60 the rate should really be $160 per hour
  - Can they change from Day 1?
  - Can they change from Day 60 forward?

BH | BAIRD HOLM LLP ATTORNEYS AT LAW
24

Payments by Physician

- Useful because no writing requirement
- Historically very limited use because of CMS narrow interpretation
- 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)

EHR Items and Services

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

New Exceptions (Non value-based)

- Limited Remuneration to a Physician
  - $5,000 annual aggregate (inflation adjusted)
    - FMV
    - No volume or value
    - Commercially reasonable
  - Can be combined with other exceptions to cure arrangements at issue when non-compliance is due to technical issues

Hypo-Limited Remuneration

- P is member of H Board
- H sends all board and spouses to AHA governance institute and pays expenses
- P reimbursed $3,000 (spousal portion taxed)
- No agreement, Compliance Officer asks about this at year end

New Exceptions (Non value-based)

- Cybersecurity and Technology Related Services
  - Nonmonetary remuneration only
  - Must be necessary and used "predominantly" to implement, maintain or reestablish cybersecurity
  - Must be in writing

Modified AKS Safe Harbors

- Personal Services and Management Safe Harbor
  - Permits compensation formula (deletion of requirement of aggregate comp set in advance)
  - Outcomes-Based Payments permitted

Modified/New AKS Safe Harbors

- 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
- Cybersecurity Technology and Related Services
- Other value-based safe harbors (stay tuned…)

BH | BAIRD HOLM LLP ATTORNEYS AT LAW

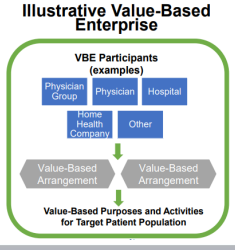
31

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

BH | BAIRD HOLM LLP ATTORNEYS AT LAW

Definitional Framework



BH | BAIRD HOLM LLP ATTORNEYS AT LAW

(Image from CMS, OIG Insights into Stark and AKS Final Rule Part 1 – Supporting Value-Based Care, presented on December 17, 2020)

Value-Based Models

- Full Financial Risk
- Substantial Downside Risk
- Care Coordination

As risk sharing goes down, compliance requirements go up

34

QUESTIONS?

35

BAIRD HOLM LLP
ATTORNEYS AT LAW

Changes and Modifications to the Stark and Anti-Kickback Rules

Andy Kloeckner
akloeckner@bairdholm.com
(402) 636-8222