




MEDAXIOM
AN ACC COMPANY

THE CHANGING RISK CLIMATE:

Updates on Compliance Rules
Governing Physician/Hospital
Arrangements

Webinar Date: January 7, 2021
Effective Date: January 19, 2021

A photograph of a person in a white lab coat holding an open book. Overlaid on the book is a scale of justice and a network of white dots connected by lines. The background is a blurred blue and white setting with hexagonal icons on the right side.

Joel Sauer, MBA
EVP of Consulting, MedAxiom
Jim Daniel, JD, MBA, CSMC, CHFP
Principal, Hancock Daniel



Jim Daniel, JD, MBA, CSMC, CHFP

Partner

Hancock Daniel

jdaniel@hancockdaniel.com



Joel Sauer, MBA

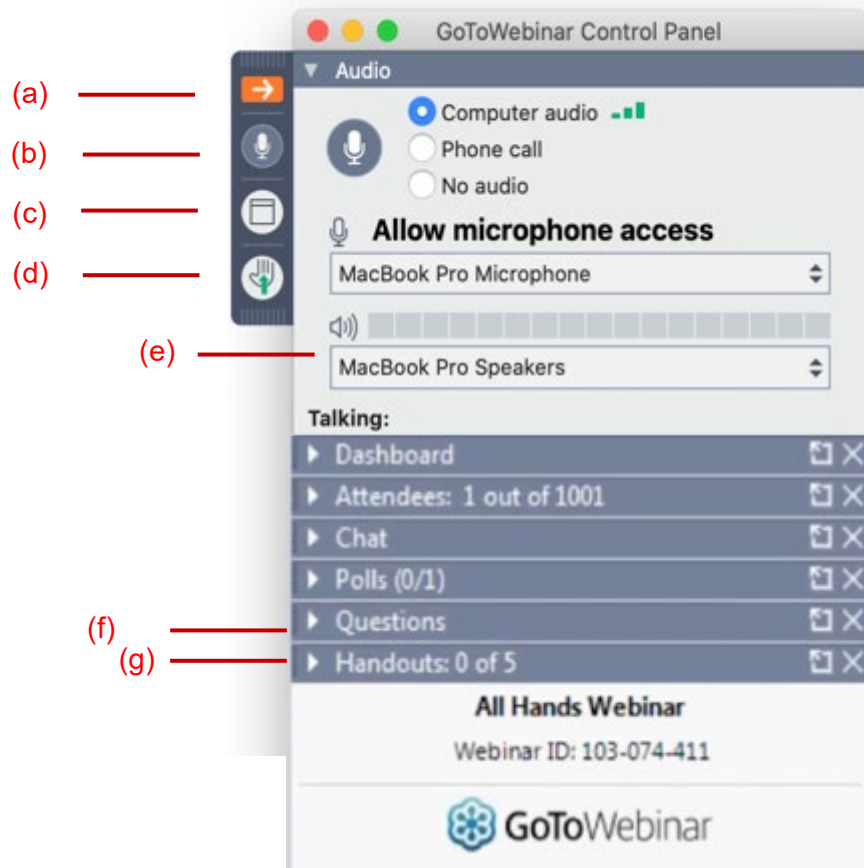
Executive Vice President of Consulting
MedAxiom

jsauer@medaxiom.com

CONTROL PANEL



MEDAXIOM
AN ACC COMPANY



(a) - Grab Tab – click arrow to open/close Control Panel.

(b) - Mute – By default, attendees are muted (in listen-only mode) to minimize background noises.

(c) - View in full screen mode

(d) - Raise Hand – When vocal questions/comments are allowed, please select the hand icon to get the presenter's attention. A red arrow means your hand is raised.

(e) - Audio Pane – You can choose Computer Audio or Phone Call.

(f) - Questions pane – Attendees can ask Questions to organizers during a session. Broadcast messages to attendees will also show here.

(g) - Handouts – Organizers can share handouts during webinars. Handouts are made available in the Control Panel during the session, which attendees can then download onto their own devices.



Value-Based Exceptions and Safe Harbors:

- New Definitions
- Stark Exceptions
- Anti-Kickback Safe Harbors



The Big Three:

- Commercially Reasonable
- Volume/Value
- FMV



Non-Value Based Changes:

- Modified/New Exceptions and Safe Harbors
- Group Practice Compensation (Stark)

“...there is broad consensus throughout the health care industry regarding the **urgent need for a movement away from legacy systems that pay for care on a FFS basis...**”

“**Identifying and addressing regulatory barriers to value-based care transformation is a critical step in this movement**”



GOALS OF THE RULES



MEDAXIOM
AN ACC COMPANY

- Remove Regulatory Barrier to Innovation
- Encourage Participation in Value-Based Arrangements
- Clarify/Simplify Existing Stark/AKS Rules

SNAPSHOT OF THE RULES



MEDAXIOM
AN ACC COMPANY

Effective January 19, 2021

Stark Law

- 5 New exceptions
- Almost every exception revised in some way
- Significant revisions and new additions to definitions and special rules on compensation

Anti-Kickback

- 7 New safe harbors
- 4 Safe harbors significantly revised

CMP Law

New exception to Remuneration (telehealth technology for home dialysis)



MEDAXIOM
AN ACC COMPANY

Changes to Value-Based Care

VALUE-BASED EXCEPTIONS AND SAFE HARBORS



MEDAXIOM
AN ACC COMPANY

| Stark | AKS |
|--|------------------------------------|
| Full Financial Risk | Full Financial Risk |
| Meaningful Downside Risk to Physician | Substantial Downside Risk (to VBE) |
| Value-Based Arrangements | Care Coordination Arrangements |
| | Patient Engagement and Support |
| Indirect Value-Based Arrangements | |
| | Personal Services Arrangements |
| Group Practice (allocation of value-based reserve) | |

Stark Anti-Kickback Both Stark and Anti-Kickback Important Stark/AKS Distinctions

NEW VALUE-BASED EXCEPTIONS AND SAFE HARBORS



MEDAXIOM
AN ACC COMPANY

Stark Exceptions

Anti-Kickback Safe Harbors

Full Financial Risk – value-based enterprise assumed full financial risk from payor for patient care for target patient population

Full Financial Risk – Value-based enterprise financial responsible for all costs covered by payor for each patient in target patient population

Meaningful Downside Financial Risk exception – value-based arrangement where physician at downside risk for failure to achieve value-based purpose

Substantial Downside Financial Risk – value-based enterprise has assumed less than full downside financial risk for *failure of VBE to achieve value-based purpose*

Value-based arrangement exception – any value-based arrangement (satisfying certain requirements)

Care Coordination Safe Harbor – coordination arrangements to improve quality, health outcomes, and efficiency

Stark Anti-Kickback Both Stark and Anti-Kickback Important Stark/AKS Distinctions

VALUE-BASED ARRANGEMENTS (STARK EXCEPTIONS)



MEDAXIOM
AN ACC COMPANY

| Element | Full Risk (VBE) | Meaningful Downside Risk (Physician) | Value-Based Arrangement |
|---|-----------------|--------------------------------------|-------------------------|
| Remuneration for/results from value-based activities | ● | ● | ● |
| Must not limit medically necessary care | ● | ● | ● |
| Not conditioned on referrals of unrelated business | ● | ● | ● |
| Required referrals must include language for patient choice and professional judgment | ● | ● | ● |
| 6-year record retention | ● | ● | ● |
| Writing Requirement | | ● (no signature req.) | ● (signed by parties) |
| Compensation methodology set in advance | | ● | ● |
| Commercial Reasonableness | | | ● |
| Outcome measures (if any) set in advance and modifications in writing | | | ● |
| Monitoring | | | ● |

FULL FINANCIAL RISK EXCEPTION AND SAFE HARBOR



MEDAXIOM
AN ACC COMPANY

- “VBE” must be *financially responsible* (or contractually obligated to be financially responsible within 12 months following the start of **value-based arrangement**)
 - **prospective basis**
 - **cost of all patient care items and services**
 - **“TPP”**
 - **specified period of time**
- Examples: *capitation payments* or *global budget payment* (other approaches to full financial risk **not** prohibited)
- Remuneration must be for/result from **value-based activities**

FULL FINANCIAL RISK EXCEPTION AND SAFE HARBOR



MEDAXIOM
AN ACC COMPANY

Other requirements:

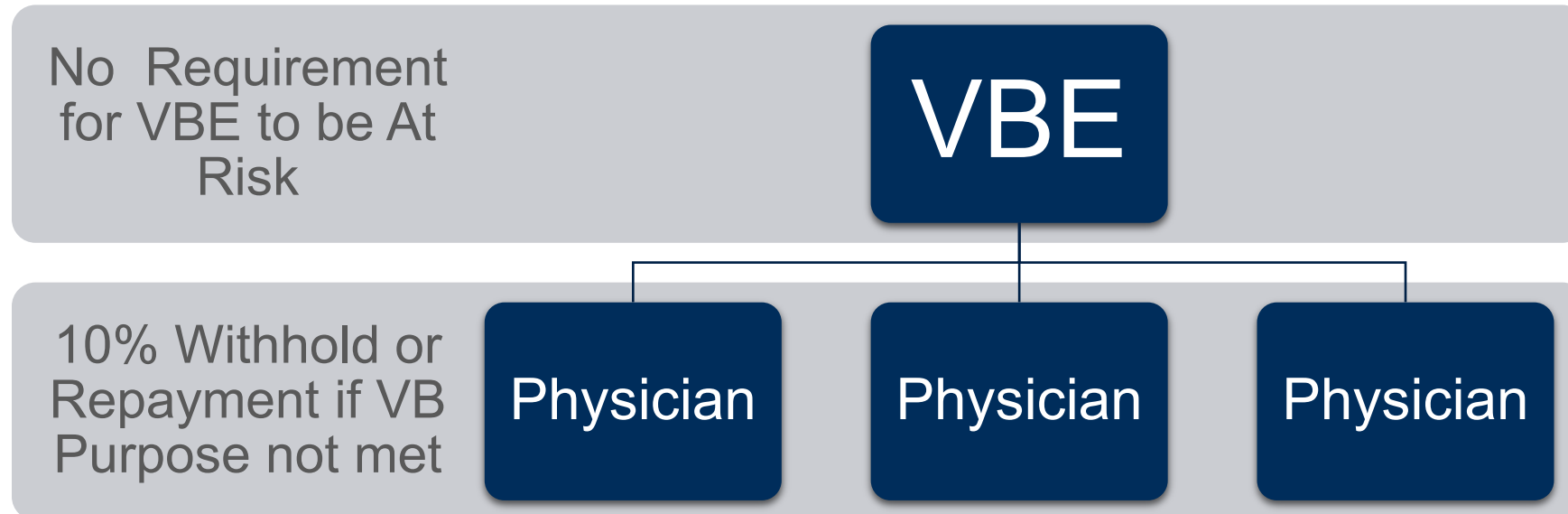
- **Does not reduce or limit medically necessary items or services** (whether in the “**target patient population**” or not)
- **Is not conditioned on referrals outside the value-based arrangement:** (patients not part of “**target patient population**” or business not covered under the “**value-based arrangement**”)
- Referrals inside the value-based arrangement meet certain criteria (Stark only): if conditioned on the physician’s referrals to a particular provider, value-based arrangement complies with both requirements
 1. must be set out in writing and signed by the parties; and
 2. may not apply if patient expresses a preference for a different provider; patient's insurer determines the provider; or referral is not in the patient's best medical interests in the physician's judgment
- **Records (methodology and amount of remuneration) maintained for at least 6 years**

Stark Anti-Kickback Both Stark and Anti-Kickback Important Stark/AKS Distinctions

MEANINGFUL DOWNSIDE FINANCIAL RISK EXCEPTION



- “**Meaningful downside financial risk**” - physician responsible to repay or forgo at least **10 percent** of total value of the remuneration the physician receives under the “value-based arrangement”
 - 10 % of *value* of the remuneration (captures in-kind remuneration)



MEANINGFUL DOWNSIDE FINANCIAL RISK EXCEPTION: REQUIREMENTS



MEDAXIOM
AN ACC COMPANY

- Meaningful downside financial risk during entire duration of value-based arrangement
- Set forth in writing (the nature and extent of the physician's financial risk)
- Methodology set in advance (methodology to determine the amount of remuneration)
- Remuneration is **for/results from** value-based activities for patients in TPP
- Does not reduce or limit medically necessary items or services (whether in the "target patient population" or not)
- Not conditioned on referrals outside the value-based arrangement (patients who are not part of the "TPP" or business not covered under the "value-based arrangement")
- Records (methodology and amount of remuneration) maintained for 6 years

MEANINGFUL DOWNSIDE FINANCIAL RISK EXCEPTION: REQUIREMENTS (CONTINUED)



MEDAXIOM
AN ACC COMPANY

- Referrals inside the “value-based arrangement” meet certain criteria:
 - If physician remuneration is conditioned on referrals to a particular provider, the “value-based arrangement” complies with both of the following conditions:
 1. set out in writing and signed by the parties; and
 2. patient preference for a different provider; patient's insurer determines the provider; or the referral is not in the patient's best medical interests in the physician's judgment (*then referral requirement does not apply*)

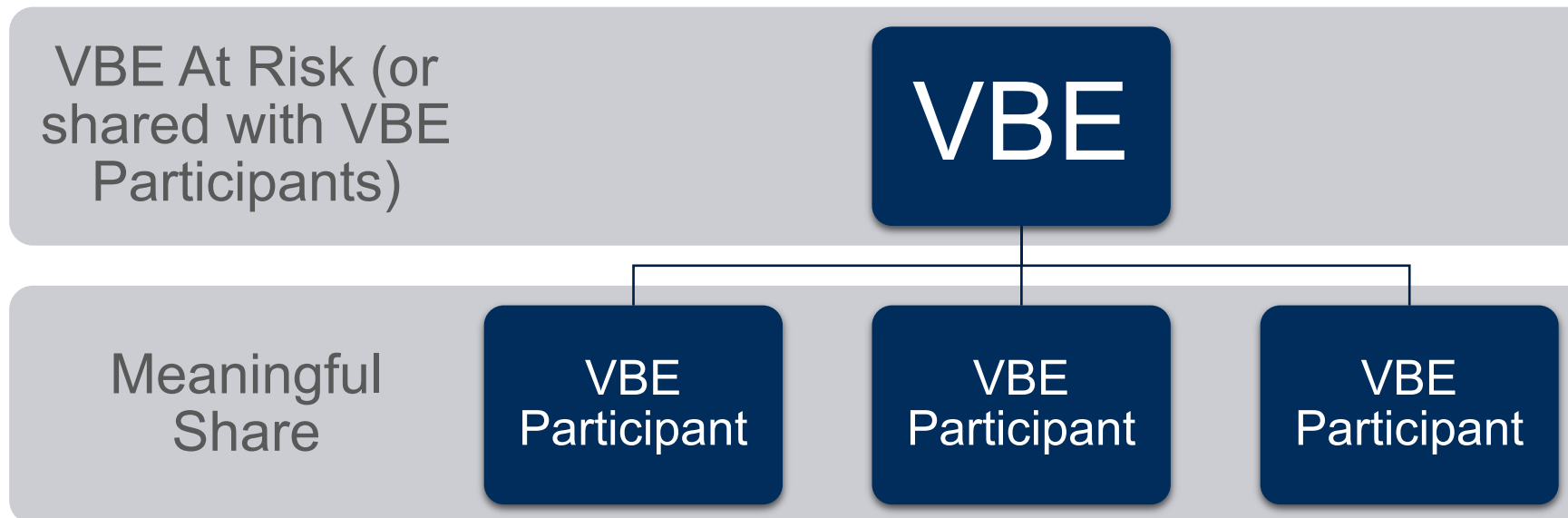
SUBSTANTIAL DOWNSIDE FINANCIAL RISK SAFE HARBOR



MEDAXIOM
AN ACC COMPANY

“**Substantial downside financial risk**” is defined as:

- At *least 30%* of any losses for **ALL** items and services furnished to “target patient population;”
- At *least 20%* of any loss for defined clinical episode of care (across multiple care settings); **OR**
- Certain partial capitation payments



SUBSTANTIAL DOWNSIDE FINANCIAL RISK SAFE HARBOR



MEDAXIOM
AN ACC COMPANY

- Remuneration provided by, or shared among, the “VBE” and “VBE participant:”
 - Is directly connected to one or more of the “VBE’s” “value-based purposes;”
 - Is used predominantly to engage in “value-based activities” directly connected to the items and services **for which the “VBE” has assumed substantial downside financial risk;**
 - Does not include the offer or receipt of an ownership or investment interest in an entity or any distributions related to such ownership or investment interest; and
 - Is not exchanged or used for the purpose of marketing items or services furnished by the “VBE” or a “VBE participant” to patients or for patient recruitment activities.

VALUE-BASED ARRANGEMENTS EXCEPTION AND CARE COORDINATION SAFE HARBOR



MEDAXIOM
AN ACC COMPANY

- New exception for compensation arrangements that qualify as **value-based arrangements**, regardless of the level of risk undertaken by the VBE or any of its VBE participants [§ 411.357(aa)(3)]
- The value-based arrangement exception would permit both *monetary* and *nonmonetary* remuneration between the parties
 - **AKS Distinction** – AKS Care Coordination Safe Harbor is limited to protect only non-monetary (in-kind) remuneration

TRANSPORTATION



MEDAXIOM
AN ACC COMPANY

- Modification to existing Safe Harbor
- Expands distance allowed for rural patients from 50→75 miles
- Removes any distance limitation at discharge (following inpatient admission or observation stay of at least 24 hours)
- Protects **nonmedical transportation offered by “VBE participants”** if such transportation has a **direct connection to the coordination and management of care** of the **“TPP”** and meets the other conditions of the safe harbor.
- Ride-sharing arrangements are permissible



- Arrangements for Patient Engagement and Support to Improve Quality, Health Outcomes, and Efficiency
- Remuneration does not include a patient engagement tool or support furnished by “VBE Participant” to patient in a “target patient population”
- Protects only in-kind remuneration
- Eligible entities to furnish, fund, or contribute support, do **not** include:
 - manufacturers, distributors, and wholesalers of pharmaceuticals;
 - pharmacy benefit managers;
 - laboratory companies;
 - pharmacies that primarily compound or dispense compounded drugs;
 - manufacturers of devices and medical supplies (unless the tool or support is digital health technology);
 - entities or individuals that sell or rent DMEPOS (other than a pharmacy, a manufacturer of a device or medical supply, or a physician, provider, or other entity that primarily furnishes services);
 - medical device distributors and wholesalers; and
 - physician-owned medical device companies.



MEDAXIOM
AN ACC COMPANY

Recharacterizing Stark's "Big Three"

THE BIG THREE



MEDAXIOM
AN ACC COMPANY

**Commercial
Reasonableness**

**Volume or Value
Standard**

Fair Market Value

Stark Anti-Kickback Both Stark and Anti-Kickback Important Stark/AKS Distinctions

NEW DEFINITION OF COMMERCIALLY REASONABLE



MEDAXIOM
AN ACC COMPANY

- **Commercially reasonable** – *the particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty.*
- An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties.
- Subjective standard.
- Combination of two proposed definitions.

COMMERCIALLY REASONABLE



MEDAXIOM
AN ACC COMPANY

- Examples provided by CMS:
 - Community need
 - Timely access to health care services
 - Fulfillment of licensure or regulatory obligations (EMTALA)
 - Charity care
 - Improvement of quality and health outcomes
- Non-exhaustive list – other examples may apply.

THE “VOLUME OR VALUE” STANDARD



MEDAXIOM
AN ACC COMPANY

- Special rule at 42 CFR §411.354(d)(5) and (6).
- No separate definition.
- Special rule establishes four objective tests:
 - V/V referrals for compensation to a physician.
 - Other business generated for compensation to a physician.
 - V/V referrals for compensation from a physician.
 - Other business generated for compensation from a physician.

THE “VOLUME OR VALUE” STANDARD



MEDAXIOM
AN ACC COMPANY

- Does the compensation formula positively or negatively correlate with the number or value or physician referrals or other business generated?
- Compensation **to** a physician - a **positive correlation** exists when one variable decreases as the other variable decreases or one variable increases as the other variable increases.
- Compensation **from** a physician - a **negative correlation** exists when one variable decreases as the other variable increases.

FAIR MARKET VALUE



MEDAXIOM
AN ACC COMPANY

- Refined definition of “general market value” and expanded application to rental arrangements.
- CMS cautioned on over-reliance on survey data – the data may not apply to the unique circumstances of the parties.
- 75th percentile compensation reported in surveys is not a ceiling and compensation under this percentile does not mean it is consistent with fair market value.
- Removes V/V standard to “disentangle” concepts.
- Any commercially reasonable methodology may be used.

FAIR MARKET VALUE DEFINITION



MEDAXIOM
AN ACC COMPANY

- **Generally** – the value in an arm’s length transaction for general commercial purposes, consistent with the general market value of the subject transaction.
- **Equipment Rentals** – for general commercial use - cannot take into account the equipment’s intended use.
- **Space Rentals** – for general commercial purposes not taking into account the intended use and without adjustment to reflect additional value of the prospective lessee or lessor would attribute to proximity or convenience to the lessor where the lessor is a potential source of referrals to lessee.

FAIR MARKET VALUE DEFINITION



MEDAXIOM
AN ACC COMPANY

- **“General Market Value”**
 - **Assets:** the price that an asset would bring on the date of acquisition as the result of bona fide bargaining between a well-informed buyer and seller that are not otherwise in a position to generate business for each other.
 - **Compensation:** Compensation that would be paid at the time the parties enter into the service arrangement as the result of a bona fide bargaining between well-informed parties that are not otherwise in a position to generate business for each other.
 - **Equipment or Office Space:** The price that rental property would bring at the time the parties enter into the rental arrangement as the result of bona fide bargaining between a well-informed lessor and lessee that are not otherwise in a position to generate business for each other.

THE BIG THREE: KEY TAKEAWAYS



MEDAXIOM
AN ACC COMPANY



1. Separation of standards.
2. New definition and guidance on what may be commercially reasonable.
3. New correlation rule for “takes into account”
4. Addresses some concerns from *Tuomey*.
5. Caution on over-reliance on surveys.
6. Compliance with CR/FMV is still based heavily on facts and circumstances.



Changes to Non-Value-Based Care



Personal Services and Management Contracts

- Modification to existing Safe Harbor
- Set in advance requirement:
 - **Aggregate compensation** → changed to **methodology for determining compensation**
- Eliminate requirement that part-time arrangements have schedule set out in written agreement



- **Outcomes-based Payment Arrangements** – Protects payments to improve patient or population health (through coordination of care or reduction in payor costs while improving quality)
- Outcome measure –
 - Selected based on clinical evidence and medical support
 - Benchmarks used to quantify improvements in quality and reduction in costs
- Outcomes-based payment –
 - For achieving outcome measure (reward) or failing to achieve (recoupment/reduction)
 - Cannot be based solely on internal cost savings, patient satisfaction, patient convenience
- Elements and Protections –
 - Methodology set in advance (FMV,CR,V/V), writing signed in advance or contemporaneous, no limit on patient choice, not less than 1-year, ongoing monitoring and assessment

PATIENT CHOICE AND DIRECTED REFERRALS



MEDAXIOM
AN ACC COMPANY

- Permits directed referrals if specific conditions are met to preserve patient choice, insurer's determinations, and protect medical judgment
- New condition – neither existence of a compensation arrangement or amount of compensation can be contingent on volume or value of referrals
- Directed referral requirement impermissible if compensation arrangement would be terminated if:
 - Physician failed to refer sufficient number of patients for DHS, **or**
 - Value of the physician's referrals of DHS failed to achieve the target established under the directed referral requirement
- May require **percentage** or **ratio** of referrals
- Would not “categorically prohibit” arrangement where physician paid different % of bonus pool based on % of physician's referrals in network

LIMITED REMUNERATION TO PHYSICIAN



MEDAXIOM
AN ACC COMPANY

- Protects remuneration from entity to physician for items or services **provided by the physician** that does not exceed an **aggregate of \$5,000** (per year)
- Can't take into account V/V of referrals or other business generated and can't exceed FMV
- Commercially reasonable even if no referrals between parties
- Compensation for **lease or use of office space/premises or equipment** can't be determined using formula based on:
 - % of revenue from service in the office space or use of equipment; or
 - Per-unit of service rental charges
- Available even when parties fail to document arrangement in a contemporaneous writing

LIMITED REMUNERATION TO PHYSICIAN



MEDAXIOM
AN ACC COMPANY

- Unless payments can be attributed to individual physician and are passed through to that physician, payments to a group practice would be allocated and count against the annual aggregate limit for each physician owner within the group practice
 - E.g. \$1,000 payment to a group practice could be treated as a \$1,000 payment to each of the physician owners of the group practice for purposes of the aggregate limit.
- Unlike most exceptions under Stark, this special new limited exception is available even where the parties fail to document the arrangement in a contemporaneous writing.

DISTRIBUTION OF DHS PROFITS WITHIN A GROUP PRACTICE



MEDAXIOM
AN ACC COMPANY

- Effective January 1, 2022, a group practice need not treat all components of at least 5 physicians the same with respect to the distribution of shares of overall profits from designated health services.
- Nothing prohibits the use of eligibility standards (e.g., some physicians in the group are eligible to participate in the profit share while others are not) provided that the eligibility standards do not result in the payment of a profit share that is directly related to the volume or value of a physician's referrals.
- Group practices (or components) may not distribute the profits from designated health services on a service-by-service basis.
- Different components consisting of at least 5 physicians (each within a group practice) are not required to use the same methodology for distributing the profits of the different components. However, a group practice component must utilize the same methodology for distributing overall profits for every physician in the component.

OTHER RELEVANT CHANGES TO GROUP PRACTICES



MEDAXIOM
AN ACC COMPANY

- New special rule applies – when determining whether the physician’s compensation, share of overall profits, or productivity bonus is based on, is directly or indirectly related to, or takes into account the volume or value of the physician’s referral to the group practice
- Profits from DHS that are directly attributable to a physician’s participation in a value-based enterprise may be distributed to the participating physician.



Q&A



Jim Daniel, JD, MBA, CSMC, CHFP
Partner
Hancock Daniel

jdaniel@hancockdaniel.com



Joel Sauer, MBA
Executive Vice President of Consulting
MedAxiom

jsauer@medaxiom.com