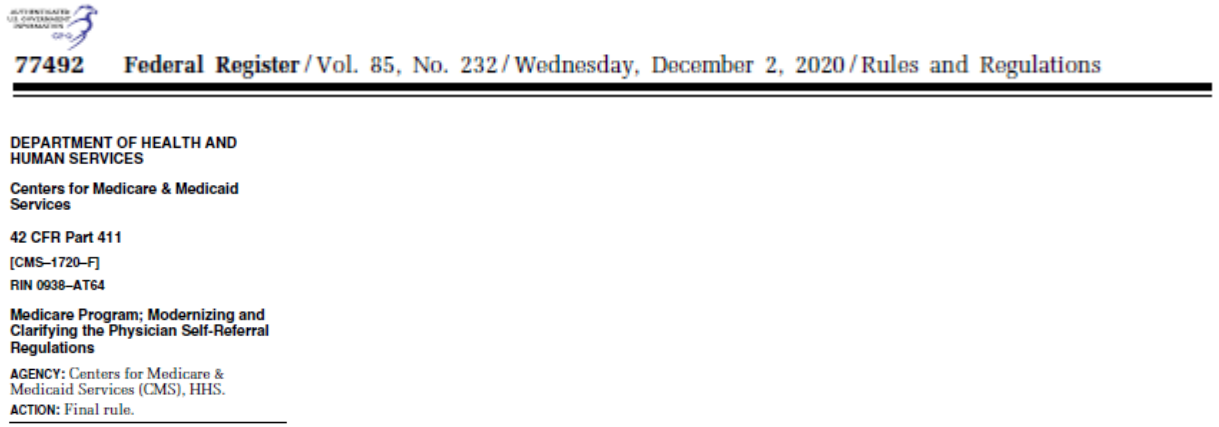

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

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Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

“Stark” Reality Ahead—New Rule Means Big Changes in 2021 to Fair Market Value, Commercial Reasonableness, and More

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Introductions

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Agenda

- Provide key takeaways surrounding the Big 3—Fair Market Value ("FMV"), Commercial Reasonableness ("CR"), and Volume or Value Standard ("V/V")
- Debunk FMV/CR myths
- Provide practical guidance and application of the Big 3
- Share an overview of the value-based care revisions
- Give key guidance surrounding group practice updates
- Explore other key takeaways

Why is FMV, CR, and V/V Important?

- Applicable to meet certain exceptions to the Stark regulations which do not allow physicians to refer patients to entities with which they have a financial relationship when designated health services are involved.
- Until now, the FMV definition included references to V/V. However, given that these two concepts are already included in several regulatory exceptions, CMS eliminated the V/V reference in the definition of FMV.

Why is FMV, CR, and V/V Important? (continued)

From CMS' "eye" -

- FMV - Did the calculation result in compensation that is fair market value for asset, item, service, or rental property?
- CR - Does the arrangement make sense as a means to accomplish the parties' goals?
- V/V - How did the parties calculate the remuneration?

FMV Definition

- In general, the value in an arm's length transaction, consistent with the general market value of the subject transaction
- General market value means -
  - Assets – The price that an asset would bring on the date of acquisition of the asset 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 – The compensation that would be paid at the time the parties enter into the service arrangement as the result of bona fide bargaining between well-informed parties that are not otherwise in a position to generate business for each other.
  - Rental of 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.

Applications of New FMV Definition

- “General market value” is not “market value,” nor is it “investment value”
- “A hospital may not value a physician’s services at a higher rate than a private equity investor or another physician practice…we recognize that reliance on similar transactions in the marketplace could simplify the process of determining fair market value for purposes of the physician self-referral law, but adopting such a standard would allow parties to consider additional (or investment) value to certain types of entities, skewing the buyer-neutral fair market value”
- Any commercially reasonable methodology may be used to establish FMV

POLLING QUESTION #1

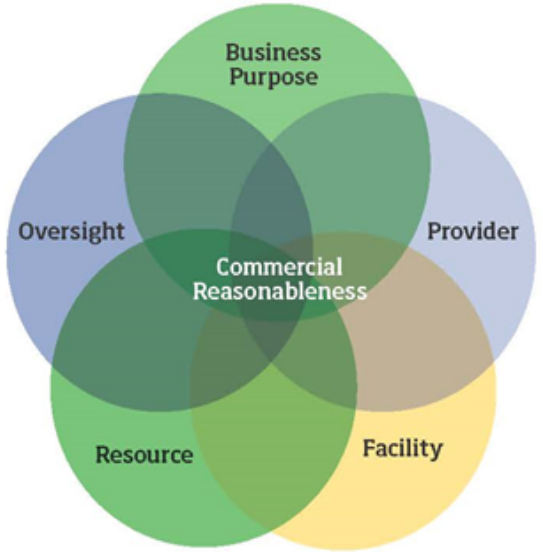
CR Definition

- **Commercially reasonable means** "… *that 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.*"

Application of New CR Definition

- Arrangements may appear to further a legitimate business purposes but may not be CR
- What is “sensible”?
  - It is not good enough just to have a legitimate business purpose – execution / ongoing re-evaluation counts
  - Five-Pronged Approach to Determining CR

Areas of Analysis to Ensure Commercial Reasonableness



Volume or Value Standard

- What does taking into account the volume or value of referrals or other business generated mean?
- CMS developed a two-part test to determine whether an arrangement meets the volume or value standard. This test includes:
  - Does a mathematical physician compensation formula exist that includes designated health service referrals or other business generated as a variable?
  - If the answer to Question #1 is “Yes,” then does a physician’s compensation increase or decrease based on a positive or negative correlation with the physician’s referrals or other business generated?

Volume or Value Standard (continued)

- As an example, suppose there is an arrangement whereby a physician compensation formula is developed that pays a physician a certain percentage of a bonus pool that includes designated health services referred by the physician to an entity
- CMS clarified that a unit-based (e.g., work relative value unit) compensation formula centered solely on a physician's personally performed services would meet the V/V standard.

POLLING QUESTION #2

FMV and CR Myths

- **Myth #1: Benchmark data determines fair market value**
  - "It appears…that stakeholders may have been under the impression that it is CMS policy that reliance on salary surveys will result, in all cases, in a determination of fair market value"
  - "The FMV of a transaction does not always align with published valuation data compilations, such a salary surveys"

FMV and CR Myths (continued)

- **Myth #2: It is CMS Policy that compensation set at or below the 75th percentile in a salary schedule is appropriate**
  - "We are uncertain why the commenters believe that it is CMS policy that compensation set at or below the 75th percentile in a salary schedule is always appropriate, and that compensation set above the 75th percentile is suspect, if not presumed inappropriate.
    The commenters are incorrect that this is
    CMS policy."

FMV and CR Myths (continued)

- **Myth #3: Arrangements cannot be commercially reasonable if they are not profitable**
  - CMS cites examples of non-profitable arrangements including those that meet community care, fulfill licensure/ regulatory obligations, and others
  - Profitability is still relevant – “We are not convinced that the profitability of an arrangement is completely irrelevant or always unrelated to the determination of CR”

Key Takeaways, Part 1

- CMS made some important clarifications, and addressed many current questions related to FMV, CR, and V/V.
- FMV and CR remain “facts and circumstances” specific, and FMV could fall above/ below survey data based on qualitative and quantitative considerations
- CMS reiterated its position that any commercially reasonable methodology is acceptable to determine FMV
- While a bright line methodology for the V/V exists, the difficulty of ensuring compliance with this standard may leave many organizations looking to third party organizations to help with this subject.

Value-Based Care Exception

- Much anticipated
- But first, definitions:
  - Value-Based Enterprise (“VBE”), Value-Based Participant
  - Value-Based Arrangement
  - Target Patient Population (“TPP”)
  - Value-Based Purpose
  - Value-Based Activity

Value-Based Care – Full Financial Risk

- To meet exception, Option 1 –
  - Be at *Full Financial Risk* – includes the cost of **all** patient care items and services covered by the applicable payer for each patient in the TPP
  - Payment is for results of Value-Based Activity for patients of the TPP
  - Payment is not an inducement to reduce or limit necessary items or services
  - Payment is not conditioned on referrals of patients *who are not part of* the TPP or business not covered by the Value-Based Arrangement

Value-Based Care – Full Financial Risk

- To meet exception (continued) –
  - If payment is conditioned on referrals of patients in the TPP, it must pass a 2-part test:
    - The requirement to make referrals (to a provider, practitioner, or supplier) is set out in writing and signed by the parties
    - The requirement to make referrals does not apply if the patient otherwise expresses a preference, the patient's insurer determines the preference, or the referral is not in the patient's best interest
  - Keep documentation supporting payments for a minimum of six years

Value-Based Care – Meaningful Downside Risk to Physician

- To meet exception, Option 2 –
  - Be at *Meaningful Downside Risk* –physician is responsible to repay or forgo no less than 10% of the total value of the payment the physician receives under the Value-Based Arrangement
  - Downside risk is in writing
  - Methodology used to determine the payment is set in advance of the undertaking of Value-Based Activities
  - All other requirements same as Full Financial Risk

Value-Based Arrangement

- To meet exception –
  - In writing and signed, including:
    - Details of the defined terms
    - The nature and methodology used to determine the payment
    - The Outcome Measures against which the physicians will be measured
      - "Outcome Measure" means a benchmark that quantifies
        - Improvements or maintenance in the quality of patient care
        - Reductions in cost or reductions in the growth of costs while maintaining the quality of patient care

A Word About Outcome Measures…

- To meet exception –
  - Outcome Measures must be:
    - Objective, measurable, and selected based on clinical evidence or credible medical support
    - Changes to the measures are made prospectively and in writing
    - Methodology for determining amount of payment is set in advance of the undertaking of Value-Based Activities
    - Payment is for results from Value-Based Activities of the physician for patients in the TPP
    - The arrangement is CR

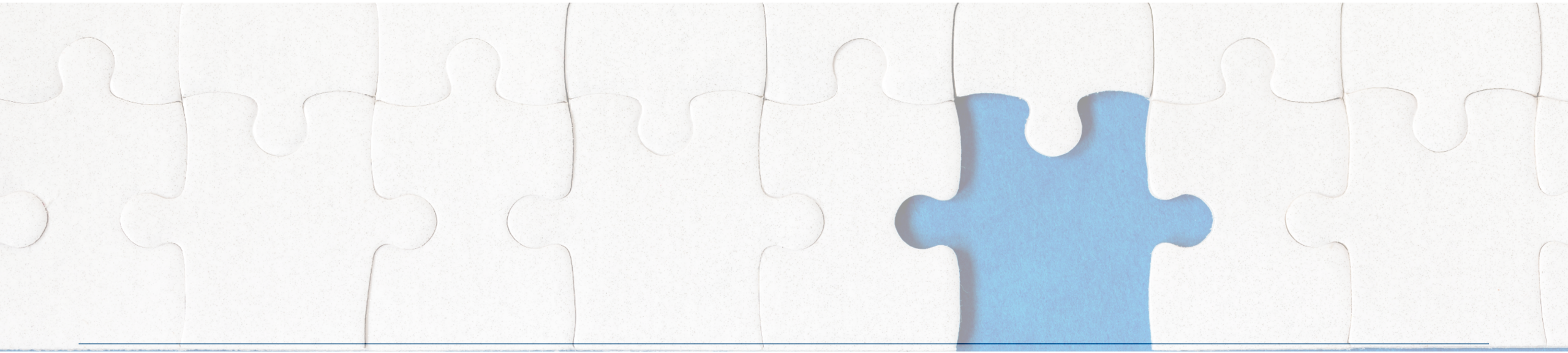
A Word About Outcome Measures…

- To meet exception –
  - Outcome measures must be:
    - Monitored at least annually by the VBE, including
      - Did the parties provide the Value-Based Activities
      - If and how the continuation of the Value-Based Activities furthers the Value-Based Purpose of the VBE
      - Progress was made toward achievement of the Outcome Measures
    - If monitoring indicates a Value-Based Activity no longer supports the Value-Based Purpose, then the ineffective Value-Based Activity must be terminated. Unattainable Outcome Measure(s) also cause termination or replacement of Outcome Measure(s).

Value-Based Exception – What is Missing?

- FMV
- V/V

However, this does not remove the requirement to "stack" value-based compensation in an employment (or other) arrangements.



POLLING QUESTION #3

Group Practice Updates

- Profit Distributions
  - Physician may be paid a share of *overall profits* if not V/V
    - "overall profits" = the profits from all DHS of any component of the group that consists of at least 5 physicians and *aggregated before distribution*
    - Groups may have different distribution formulas for different sub-groups within the group
    - Profit shares based on *profits* of the group, *not revenues*
  - Groups may distribute VBE profits directly to a physician
    - Includes profits from DHS

Group Practice Updates

- Productivity Bonuses may be based on
  - Services personally performed
  - Services incident-to
  - Both
- Productivity Bonuses may not be based on
  - V/V

Other

- Cybersecurity Technology Exception – Such technology may be donated to a physician if the donation is not contingent upon V/V, donation is not a condition of doing business with the donor, and the arrangement is documented in writing
  - Aligns with Anti-Kickback Statute Final Rule
- Limited Remuneration Exception – Increased to $5,000; FMV, V/V, and CR apply but arrangement does not have to be documented
- Writing and Signature Requirements – Allows electronic signature, a collection of documents for signature, within 90 days of agreement start

Key Takeaways, Part 2

- Explore current Value-Based Arrangements
  - Opens opportunities for hospital integration with independent physicians
- Review Group Practice profit distributions
  - Ensure based on profits and not revenues
  - Consider modifications within sub-groups
- Review Group Practice productivity bonus formulas
  - Ensure not V/V based on new guidance

How can we HELP?