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COMMERCIAL REASONABLENESS AND VALUE-BASED ARRANGEMENTS:

KNOW YOUR WHY AND HOW

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Although commercial reasonableness has been a key concept in healthcare regulation since 1998, it was not until 2021 that it received a regulatory definition in 42 CFR § 411.351, as follows: *"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."*

This definition established two important concepts. First, commercial reasonableness is subjective to the parties of the specific arrangement and not a hypothetical transaction. Second, while profit is not irrelevant to the determination of commercial reasonableness, arrangements need not generate a profit to be commercially reasonable.

42 CFR § 411.351 also introduced a new exception for arrangements "that facilitate value-based health care delivery and payment" (42 CFR § 411.357(aa)). Notably, this exception excludes common requirements that compensation under the arrangement must be consistent with fair market value and not determined in a manner that takes into account the volume or value of a physician's referrals. Thus, one might conclude that CMS has thrown caution to the wind in its efforts to remove barriers to market innovation to achieve better health outcomes. However, deep within the exception is a requirement for "no-risk" arrangements that serves as the governor on runaway innovation and, potentially, abusive arrangements: *"The arrangement [must be] commercially reasonable."*

The phrase, "legitimate business purpose" is important in establishing commercial reasonableness under the value-based exception, because the "purpose" of the value-based enterprise is defined in the regulations. Given the broad definition of the value-based purpose, along with clarification that the value-based arrangement need not be profitable to be commercially reasonable, CMS has provided organizations with significant flexibility to satisfy the commercial reasonableness requirement.

However, the concepts of commercial reasonableness and FMV historically have been intertwined. Inherent in the commercial reasonableness of an arrangement is the expectation that the financial components are FMV. While the two terms are now distinctly defined, it remains to be seen how relators, enforcement agencies, and the courts will separate these concepts.

For now, organizations may consult prior CMS commentary regarding commercially "unreasonable" arrangements for guidance as to whether their value-based arrangement may pass the new standard. Much of this commentary focused on duplication of roles and associated payments or unnecessary arrangements. For example, redundant medical directorships or unnecessary space leases.

Similarly, when value-based incentives are paid to employed physicians, there may be "spillover" into the employment agreement, the core terms of which likely fall under the employment exception. There may be both FMV and commercial reasonableness implications if these incentives duplicate quality bonuses, medical director payments, or other compensation contained in the underlying employment agreement. If value-based payments to employed physicians exacerbate practice losses, this may also implicate the FMV and/or commercial reasonableness requirements under the employment exception.

Although profit is not necessary, organizations should be prepared to quantify and justify unprofitable investments in the context of the value-based purpose. For example, if the value-based enterprise obtains management services from a related party, organizations may desire to establish that payment from the enterprise to the MSO is commercially reasonable and FMV.

Finally, establishing that remuneration to physicians is the result of activities performed by the recipients is critical to linking payments to the value-based purpose. Arrangements that guarantee distributions without tying them to specific activities or appropriate outcomes may face commercial reasonableness challenges. The parties must periodically assess and, as necessary, revise the quality measures and benchmarks used to determine incentive payments. "Maintaining" quality or "reducing" costs as standalone objectives are not sufficient to support the value-based purpose.

With this new exception, CMS has granted organizations considerable latitude in establishing value-based arrangements. However, as with any arrangement, thoughtful documentation that answers the question as to "why" the parties are entering into the arrangement, and "how" the arrangement furthers the value-based purpose, will be useful to address any commercial reasonableness concerns.