Transition to Value-Based Care

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Disclaimer: This document is not meant to provide legal guidance/advice. The author has relied on language provided by HHS and OIG through the release of Federal Register / Vol. 85, No. 232 / Wednesday, December 2, 2020 / Rules and Regulations to provide a summary of the Value-Based Care Final Rule. All definitions and examples provided are specific to those provided in the aforementioned section of the Federal Register. To ensure compliance with the Final Rule related to VBC contact your healthcare attorney. The author nor DoctorsManagement, LLC assume any responsibility for individuals who use this summary document without proper guidance from their own legal counsel.

Under the "Modernizing and Clarifying the Physician Self-Referral Regulations, the transition to Value-Based Care (VBC) the government looked at the "Regulatory Spirit to Coordinated Care" to create guidance and Exceptions. "The Department identified the broad reach of the physician self-referral law, as well as the Federal anti-kickback statute and beneficiary inducements civil monetary penalty (CMP) law, sections 1128B(b) and 1128A(a)(5) of the Act, respectively, as potentially inhibiting beneficial arrangements that would advance the transition to value-based care and the coordination of care among providers in both the Federal and commercial sectors." It should be known that the Regulatory Spirit "Aims to remove potential regulatory barriers to care coordination and value-based care created by four key Federal health care laws and associated regulations: (1) The physician self-referral law; (2) the antikickback statute; (3) the Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191) (HIPAA); and (4) the rules under 42 CFR part 2 related to opioid and substance use disorder treatment."

There are four (4) aspects the HHS' Regulatory Sprint aims to encourage and improve

- A patient's ability to understand treatment plans and make empowered decisions;
- Providers' alignment on an end-to end treatment approach (that is, coordination among providers along the patient's full care journey);
- Incentives for providers to coordinate, collaborate, and provide patients with tools to be more involved; and
- Information-sharing among providers, facilities, and other stakeholders in a manner that facilitates efficient care while preserving and protecting patient access to data.

When the Stark Law (Physician Self-Referral Statutes was enacted in 1989 under Medicare's traditional Fee for Service (FFS) Medicare payments were volume-based even though we had some bundled services. The focus became on designated health services (DHS) since the more services a provider rendered the more payments they received from Medicare. The way the statute works in the practical world is simple, if a referring physician has ownership or investment interest in an entity furnishing DHS, they could increase the entity's revenue by referring patients for higher value services, thus in theory (or reality) increase profit distributions tied to providers' ownership interest. Additionally, providers that have service or compensation arrangements with that entity might increase their aggregate compensation if they make referrals resulting in more Medicare payments to the entity. The statute was enacted to combat financial self-interest that could affect a physician's medical decision making and ensure patients have options for quality care. At the time the statute was enacted to HHS this made sense since Medicare's then-largely volume-based reimbursement system didn't take value into consideration. For the sake of keeping this article reasonably sized I am not addressing Section 3022 of the Affordable Care Act, which established and deals with the Medicare Shared Savings Program…

In the October 17, 2019 Federal Register, OIG published a proposed rule under the anti-kickback statute and CMP law to address concerns regarding provisions in those statutes that may act as barriers to coordinated care (84 FR 55694). Many compensation arrangements between parties participating in alternative payment models and other novel financial arrangements implicate both the physician self-referral law and the anti-kickback statute. HHS is working to "promote alignment across agencies to ease the compliance burden on the regulated industry". In the proposed rule, it was stated for some arrangements, it may be appropriate for the anti-kickback statute, which is an intent-based criminal law, to serve as ''backstop'' protection for arrangements that might be protected by an exception to the strict liability physician self-referral law (84 FR 55772). The intent in interpreting and implementing section 1877 of the Act according to HHS has always been ''to interpret the [referral and billing] prohibitions narrowly and the exceptions broadly, to the extent consistent with statutory language and intent.'' (84 FR 55771; see also, 66 FR 860).

The purpose of the final rule is to modernize and clarify the statute. The final rule also includes clarifying provisions and guidance intended to reduce unnecessary regulatory burden on health care providers and suppliers, while reinforcing the law's goal of protecting against program and patient abuse. New exceptions are being created for non-abusive arrangements for which there is currently no applicable exception to the law's referral and billing prohibitions. There are several provisions of the Final Rule for

facilitating the transition to VBC and fostering care coordination. As part of the Final Rule, there is a new set of definitions and exceptions which depart from the historic exceptions to the law which facilitate the transition to a VBC delivery and payment system. You will note that the final definitions and exceptions that pertain to the physician self-referral law differ in some respects from the final definitions and safe harbors that pertain to the anti-kickback statute. Compensation arrangements may implicate both statutes and, therefore, should be analyzed for compliance with each statute.

These are the definitions and exceptions found in § 411.357(aa), and it should be noted that the exceptions apply regardless of whether the arrangement relates to care furnished to Medicare beneficiaries, non-Medicare patients, or a combination of both. Also, nothing in the final policies is intended to suggest that many value-based arrangements, such as pay-for-performance arrangements or certain risk-sharing arrangements, do not satisfy the requirements of existing exceptions to the law. The new definitions at § 411.351 are for the following terms:

- Value-based activity;
- value-based arrangement;
- value-based enterprise;
- value-based purpose;
- VBE participant; and target patient population.

It should also be of note that with respect to the value-based terminology as defined in the final rule, HHS has aligned themselves with OIG for the most part. There are point of difference and those should be looked at carefully by your compliance and legal expert(s). In the proposed rule (84 FR 55773), the following terms and definitions for purposes of applying the new exceptions at § 411.357(aa) were released and include:

> • Value-based activity means any of the following activities, provided that the activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise: (1) The provision of an item or service; (2) the taking of an action; or (3) the refraining from taking an action. We also proposed that the making of a referral is not a value-based activity.
> • Value-based arrangement means an arrangement for the provision of at least one value-based activity for a target patient population between or among: (1) The value-based enterprise and one or more of its VBE participants; or (2) VBE participants in the same value-based enterprise.

• Value-based enterprise means two or more VBE participants: (1) Collaborating to achieve at least one value-based purpose; (2) each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the value-based enterprise; (3) that have an accountable body or person responsible for financial and operational oversight of the value-based enterprise; and (4) that have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s).

• Value-based purpose means: (1) Coordinating and managing the care of a target patient population; (2) improving the quality of care for a target patient population; (3) appropriately reducing the costs to, or growth in expenditures of, payors without reducing the quality of care for a target patient population; or (4) transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.

• VBE participant means an individual or entity that engages in at least one value-based activity as part of a value-based enterprise.

• Target patient population means an identified patient population selected by a value-based enterprise or its VBE participants based on legitimate and verifiable criteria that are set out in writing in advance of the commencement of the value-based arrangement and further the value-based enterprise's value-based purpose(s).

The definitions have been finalized with some modifications. At final § 411.351, ''value-based activity'' is defined to mean the provision of an item or service, the taking of an action, or the refraining from taking an action, provided that the activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise of which the parties to the arrangement are participants. In the proposed rule, it was stated that "the act of referring patients for designated health services is itself not a value-based activity". The final rule goes on to state, "As a general matter, referrals are not items or services for which a physician may be compensated under the physician self-referral law, and payments for referrals are antithetical to the purpose of the statute (84 FR 55773)". The definition of ''value-based activity'' means the making of a referral is not a value-based activity in order to make clear that the exceptions would not protect the direct payment for referrals. However, the definition of ''referral'' at § 411.351 is to affirm policy that, "As a general matter, referrals are not items or services for which a physician may be compensated under the physician self-referral law and, the final definition of ''value-based activity'' requires that the activities must be reasonably designed to achieve at least one value-based purpose of the value-based enterprise". HHS provides the following example, "if the value-based

purpose of the enterprise is to coordinate and manage the care of patients who undergo lower extremity joint replacement procedures, a value-based arrangement might require routine post-discharge meetings between a hospital and the physician primarily responsible for the care of the patient following discharge from the hospital. The value-based activity—that is, the physician's participation in the post-discharge meetings—would be reasonably designed to achieve the enterprise's value-based purpose. In contrast, if the value-based purpose of the enterprise is to reduce the costs to or growth in expenditures of payors while improving or maintaining the quality of care for the target patient population, providing patient care services (the purported value-based activity) without monitoring their utilization would not appear to be reasonably designed to achieve that purpose".

The definition of ''value-based arrangement'', the final exceptions apply only to arrangements that qualify as value-based arrangements. At final § 411.351, ''value-based arrangement'' is defined to mean an arrangement for the provision of at least one value-based activity for a target patient population to which the only parties are: (1) A value-based enterprise and one or more of its VBE participants; or (2) VBE participants in the same value-based enterprise. HHS revised the language of the proposed definition by substituting *''to which the only parties are'' for ''between or among''* to make clear that all parties to the value-based arrangement must be VBE participants in the same value-based enterprise. The term ''providers'' includes both providers and suppliers as those terms are defined in 42 CFR 400.202, as well as other components of the health care system. As an example, a value-based arrangement between an imaging center and a physician would not be a value-based arrangement if the imaging center is not part of the same value-based enterprise as the physician. Effectively, the parties to a value-based arrangement must include an entity (as defined at § 411.351) and a physician; otherwise, the physician self-referral law's prohibitions would not be implicated. Also, because the exceptions at final § 411.357(aa) apply only to compensation arrangements (as defined at § 411.354(c)), the value-based arrangement must be a compensation arrangement and not another type of financial relationship to which the physician self-referral law applies.

HHS at final § 411.351, value-based enterprise is defined to mean two or more VBE participants: (1) Collaborating to achieve at least one value-based purpose; (2) each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the value-based enterprise; (3) that have an accountable body or person responsible for the financial and operational oversight of the value-based enterprise; and (4) that have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s). A ''value-based enterprise''

includes only organized groups of health care providers, suppliers, and other components of the health care system collaborating to achieve the goals of a value-based health care delivery and payment system.

- An ‘‘enterprise’’ may be a distinct legal entity—such as an ACO—with a formal governing body, operating agreement or bylaws, and the ability to receive payment on behalf of its affiliated health care providers (84 FR 55774).
- An ‘‘enterprise’’ may also consist only of the two parties to a value-based arrangement with the written documentation recording the arrangement serving as the required governing document that describes the enterprise and how the parties intend to achieve its value-based purpose(s). Whatever its size and structure, a value-based enterprise is essentially a network of participants (such as clinicians, providers, and suppliers) that have agreed to collaborate with regard to a target patient population to put the patient at the center of care through care coordination, increase efficiencies in the delivery of care, and improve outcomes for patients.

The definition of ‘‘value-based enterprise’’ finalized at § 411.351 is focused on the functions of the enterprise and does not dictate or limit the appropriate legal structures for qualifying as a value-based enterprise. To qualify as a value-based enterprise each participant in the enterprise, referred to as a VBE participant, must be a party to at least one value-based arrangement with at least one other participant in the enterprise. If a value-based enterprise is comprised of only two VBE participants, they must have at least one value-based arrangement with each other in order for the enterprise to qualify as a value-based enterprise. (Provided that a value-based enterprise exists, an arrangement between the enterprise and a physician who is a VBE participant in the value-based enterprise may qualify as a ‘‘value-based arrangement’’ for purposes of the exceptions at § 411.357(aa) if the value-based enterprise is itself an ‘‘entity’’ as defined at § 411.351.)

In addition, a value-based enterprise must have an accountable body or person that is responsible for the financial and operational oversight of the enterprise. This may be the governing board, a committee of the governing board, or a corporate officer of the legal entity that is the value-based enterprise, or this may be the party to a value-based arrangement that is designated as being responsible for the financial and operational oversight of the arrangement between the parties (for example, if the ‘‘enterprise’’ consists of just the two parties).

Finally, a value-based enterprise must have a governing document that describes the enterprise and how its VBE participants intend to achieve its value-based purpose(s). Implicit in this requirement is that the value-based enterprise must have at least one value-based purpose. Also, critical to qualifying as a value-based arrangement are the scope and objective of the arrangement. Only an arrangement for activities that are reasonably designed to achieve at least one of the value-based enterprise's value-based purposes may qualify as a value-based arrangement to which the exceptions at § 411.357(aa) apply. At final § 411.351, value-based purpose is defined to mean: (1) Coordinating and managing the care of a target patient population; (2) improving the quality of care for a target patient population; (3) appropriately reducing the costs to or growth in expenditures of payors without reducing the quality of care for a target patient population; or (4) transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.

The definition of ''value-based purpose'' identifies four core goals related to a target patient population. One or more of these goals must anchor the activities underlying every compensation arrangement that qualifies as a value-based arrangement to which the exceptions at final § 411.357(aa) apply.

At final § 411.351, ''VBE participant'' is defined to mean a person or entity that engages in at least one value-based activity as part of a value-based enterprise. The definition of ''VBE participant'' does not exclude any specific persons, entities, or organizations from qualifying as a VBE participant. Lastly, HHS finalized the definition of ''target patient population''. Specifically, the target patient population for which VBE participants undertake value-based activities is defined at final § 411.351 to mean an identified patient population selected by a value-based enterprise or its VBE participants based on legitimate and verifiable criteria that: (1) Are set out in writing in advance of the commencement of the value-based arrangement; and (2) further the value-based enterprise's value-based purpose(s). The final rule affirms that legitimate and verifiable criteria may include medical or health characteristics (for example, patients undergoing knee replacement surgery or patients with newly diagnosed type 2 diabetes), geographic characteristics (for example, all patients in an identified county or set of zip codes), payor status (for example, all patients with a particular health insurance plan or payor), or other defining characteristics. Selecting a target patient population consisting of only lucrative or adherent patients (cherry-picking) and avoiding costly or noncompliant patients (lemon-dropping) would not be permissible under most circumstances, as HHS would not consider the selection criteria to be legitimate (even if verifiable) (84 FR 55776).

The Comments Portion begin on 77499 and provide much needed insight(s) into transitions between the proposed and final rule regarding VBC…

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