‘Regulatory Sprint’ reduces Stark and Anti-Kickback obstacles to coordinated care

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“Lead, follow, or get out of the way,” goes the old admonition, attributed variously to Thomas Paine, Gen. George S. Patton and Chrysler’s Lee Iacocca. When it comes to innovative health payment mechanisms, the Department of Health and Human Services (DHHS) has chosen the third path by adopting what they dubbed the “Regulatory Sprint to Coordinated Care,” beginning in 2018. The goal of this initiative is to remove or reduce regulatory obstacles that have frustrated the development and growth of alternatives to the traditional fee-for-service payment system, and to facilitate the transition toward value-based coordinated care models. Among the hurdles targeted for removal are elements of the Stark physician referral law (Stark), the Medicare and Medicaid Anti-Kickback statute (AKS) and the Civil Monetary Penalties Law (CMPL).

Proposed regulations creating new exceptions to each of these laws for a variety of value-based models, along with changes clarifying and modifying existing rules, were published Oct. 17, 2019. Final regulations were published in the Federal Register Dec. 2, 2020, and will generally take effect Jan. 19, 2021.

The Stark Law is interpreted and enforced primarily by the Centers for Medicare and Medicaid Services (CMS), an agency under the DHHS. It is a “strict liability” statute which does not require proof of improper intent to establish a violation. It prohibits any physician who has a financial relationship with a provider of certain designated health services (DHS) from referring Medicare and Medicaid patients to that provider for such DHS unless an exception is met. The AKS prohibits kickbacks or other remuneration in exchange for referrals of any item or service payable by a federal program, and requires evidence of intent. It is interpreted and enforced by the Office of Inspector General (OIG) of DHHS. The CMPL includes a prohibition on inducements to Medicare and Medicaid beneficiaries intended to encourage them to obtain goods or services payable by those programs.

Key common definitions

CMS and OIG coordinated the development of these new regulations and adopted a number of common definitions applicable across multiple statutory schemes. Note that many of these definitions refer to each other. So, let’s start the new year with a fresh bowl of governmental alphabet soup:

Value-based arrangement means an arrangement for the provision of at least one value-based activity for a target patient population which includes the value-based enterprise (VBE) and one or more of VBE participants.

Value-based enterprise (VBE) means two or more VBE participants collaborating to achieve at least one value-based purpose, 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, that have an accountable body or person responsible for the financial and operational oversight of the value-based enterprise, and that have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s). VBEs may take many forms, including Integrated Delivery Systems, Accountable Care Organizations (ACOs), Clinically Integrated Networks (CINs) as well as providers participating in certain bundled payment or episode of care models, patient-centered medical homes and similar alternative payment methodologies if the criteria listed above are met.

Value-based purpose means any of the following: (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 healthcare delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care

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and control of costs of care for a target patient population.

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

Target patient population means an identified patient population selected by a VBE or its participants based on legitimate and verifiable criteria 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). Note that "cherry-picking" the healthiest patients or "lemon-dropping" expensive, high-risk patients is prohibited.

Value-based activity means providing an item or service, taking an action or refraining from an action, provided that the activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise. In other words, it's what a VBE does to realize its value-based purposes.

Stark Law

New exceptions are added for payments under value-based arrangements if they involve *full financial risk* for all costs of care for a target patient population for a 12-month period, or if physicians assume *meaningful downside risk,* i.e., at least 10% of the value of the remuneration must be subject to forfeiture or repayment. (Note that the counterpart AKS safe harbor only requires 5% risk.) Payments may not be conditioned on referrals of patients outside of the target population, or on services not covered under the value-based arrangement.

The Stark rule fine-tuned its definition of *fair market value* to mean the price (or rental payments) that assets or services would bring as the result of bona fide bargaining between well-informed parties that are not otherwise in a position to generate business for each other, based on an individualized determination. Rental value may not take into account the intended use or proximity to referral sources.

One welcome change acknowledged that the term *commercially reasonable* may be satisfied even if it does not result in a profit for one or more of the parties. For example, a health system may employ or contract with a specialist to serve its patients even if the volume of specialty work in the community is insufficient to support the fair market costs of recruiting and compensating that specialist. Failure to break even does not automatically mean an arrangement is improper.

The final rule did restrict the ability of a group practice to pay its physicians (or subgroups of at least five physicians) a share of *overall profits* from designated health services. The new rule requires that *all DHS revenue* from all types of services be pooled and divided in the aggregate, instead of service-by-service. In the past, it was believed that a group practice could, for example, divide its physical therapy profits among one group or using one formula, and divide its imaging revenue using a different method. CMS recognized that there would not be sufficient time to change existing formulas by the beginning of 2021, so this new requirement will not take effect until Jan. 1, 2022.

Errors in calculating compensation may be reconciled within 90 days following the termination of an arrangement without violating Stark. Similarly, there is a new 90-day grace period for obtaining signatures on new or expired compensation arrangements.

A compensation arrangement may meet the *set in advance* requirement even if it is prospectively modified more frequently than once every year, so long as it is compliant at time of modification. Such prospective changes still may not be based on the volume or value of referrals.

A new exception permits *limited remuneration to physicians* for services rendered of no more than $5,000 per year, adjusted annually. Such payments must be set at fair market value, commercially reasonable and not based on the volume or value of referrals, but need not be in writing or set in advance.

Anti-Kickback Statute

Several new safe harbors were finalized for value-based arrangements: The first protects arrangements which undertake *full financial risk,* so long as remuneration does not induce the reduction or limitation of services and is not conditioned on referrals of patients not part of the target population. Any required referrals are subject to the standard "three exceptions" (patient preference, insurance requirements and the referring physician's clinical judgement).

The next involves *meaningful downside financial risk,* which requires the VBE to assume risk of at least 30% of global payments, 20% downside for episode risk, or partial capitation, and requires each VBE Participant to risk at least 5% or accept partial capitation for specific services.

The new *Care Coordination* safe harbor does not require any downside risk, but only protects in-kind assistance such as technology does require a written agreement, a system of outcomes measurement, contribution of at least 15% of the cost of any in-kind

items provided, and monitoring and assessment by the VBE.

Certain entities remain ineligible for the new value-based safe harbors, including compounding pharmacies device/DME manufacturers and DME suppliers (except for in-kind digital technology), laboratories, pharmacy benefit managers and physician-owned distributorships.

The existing safe harbor for personal service agreements was modified to remove the onerous requirement that arrangements for periodic, sporadic or part-time services specify exactly the schedule of such intervals, their precise length and the exact charge for such intervals.

An exception for *Patient Engagement and Support* permits in-kind items to be provided to patients so long as there is a direct connection to coordination and management of care, and are valued at no more than $500 per year. These items can include health-related technology such as blood pressure monitors or pulse oximeters; certain gift cards to encourage healthier habits; utility and internet access assistance; and even temporary housing for homeless individuals. This change loosens the prior CMPL rule that prohibited any remuneration to beneficiaries that may induce them to select a particular provider.

A clear path ahead?

The final rules under the Regulatory Sprint are intended to clear a path for a faster transition to value-based payment models. Nationally, these models have been more broadly adopted by private payors than by Medicare and Medicaid, although Western Pennsylvania lags behind the national trends. It is anticipated that, with fewer regulatory hurdles, both governmental and private payors will accelerate the development of new payment methods that will incentivize the coordination of effective, evidence-based clinical decision-making across the spectrum of care and bend the cost curve downward.

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