ARTICLE

Stark Law Revisions

One of Many Factors in Value-based Care

The Department of Health and Human Services released final rules on November 20, 2020 with changes to the Physician Self-Referral Law (Stark Law) and the Anti-Kickback Statute (AKS) to facilitate care coordination and value-based care. In this article we discuss the Stark Law, AKS and changes thereto, as well as implications. An operational "bottom line" perspective is also provided.

The Anti-Kickback Statute

is a criminal law that prohibits the knowing and willful payment of remuneration to induce or reward patient referrals or the generation of business involving any item or service payable by the Federal health care programs (e.g., drugs, supplies, or health care services for Medicare or Medicaid patients). Remuneration includes anything of value and can take many forms besides cash, such as free rent, expensive hotel stays and meals, and excessive compensation for medical directorships or consultancies.[2]

Stark Law and Anti-Kickback Statute

The Physician Self-Referral Law, also known as the Stark Law, prohibits physicians from referring patients to "designated health services" that are payable by Medicare or Medicaid from entities with which the physician or an immediate family member has a financial relationship, unless an exception applies. Financial relationships include both ownership and investment interests, as well as compensation arrangements. "Designated health services" include clinical lab services, physical therapy, occupational therapy and outpatient speech-language pathology services, radiology, DME and supplies, parenteral and enteral nutrients, prosthetics, home health services, outpatient prescription drugs, and inpatient and outpatient hospital services.[1]

Implications

According to Seema Verma, former administrator of the Centers for Medicare & Medicaid Services (CMS), the original, outdated

Stark has "hindered, rather than advanced, the cause of affordable, quality health care for patients."[3]

The transition from fee-for-service to value-based care is complex and requires payment reform and care delivery transformation, and patient centricity. Shared savings, downside risk, and episode-based, per member per month and global payments represent alternative financial approaches for value creation. Care delivery transformation is focused on proactive and earlier intervention, care coordination, case management and home (non-facility) centricity. Patient centricity requires increased engagement and self-management. In summary, a lot of changes are necessary that require coordination, investment and the use of financial incentives to drive the efficiency and effectiveness of care delivery.

Alternative Payment Model Framework

Category 1:

Payments are based on volume of services and not linked to quality or efficiency.

Category 2:

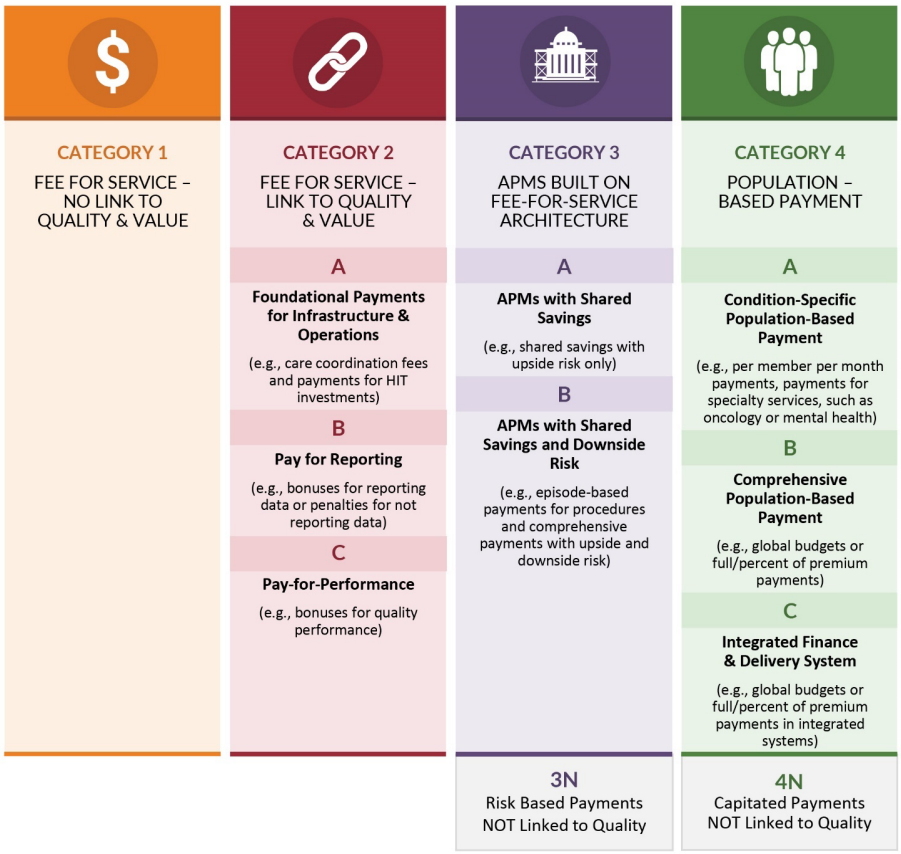
At least a quarter of payments vary based on quality or efficiency of healthcare delivery.

Category 3:

Some payment is linked to the effective management of a segment of the population or an episode of care. Payments are still triggered by delivery of services, but there are opportunities for shared savings or two-sided risk.

Category 4:

Payment not directly triggered by service delivery, so payment is not linked to volume. Clinicians and organizations are paid and responsible for the care of the beneficiary for a long period (>1 year).



Source: Healthcare Payment Learning & Action Network, 2017 http://hcp-lan.org/workproducts/apm-refresh-whitepaper-final.pdf

An example from Verma's article in Health Affairs highlights a limitation of the pre-existing Stark Law: "If the cardiology practice pays for data analytics that analyze risk factors for the primary care practice's patients, it would be unable to simply give this information to the primary care practice" (without charging a fair market price, since it gets referrals from the primary care practice).[4]

Provision of electronic medical record access to physicians has also been a Stark Law concern due to the cost of cybersecurity initiatives that may not have been passed on to system users. And lastly, compliance costs have been exceedingly high, largely due to uncertainty associated with the Stark Law and Anti-Kickback Statute provisions.

Revisions to Stark Law and Anti-Kickback Statute

The revisions are focused on facilitating care coordination and value-based [compensation] arrangements, effective January 19, 2021. Aspects of the "group practice" definition, beyond the scope of this article, do not go into effect until January 1, 2022.

According to Nixon Gwilt Law:
The new Stark exceptions are accessible

— to *value-based enterprise* (VBE) participants
— in the same *value-based enterprise* (VBE)
— who participate in *value-based activities*
— conducted under a *value-based arrangement*
— for a *value-based purpose*.[5]

According to CMS, "whatever its size and structure, a value-based enterprise is essentially a network of participants 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."[6]

As described in the Waller law blog, a value-based enterprise must comprise at least two 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"; and the participants "have an accountable body or person responsible for financial and operational oversight of the value-based enterprise" and "have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose.[7]

Value-based activities 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."[8]

A *value-based arrangement* is defined by CMS and OIG as "an arrangement for the provision of at least one value-based activity for a target patient population to which the only parties are (A) the value-based enterprise and one or more of its VBE participants; or (B) VBE participants in the same value-based enterprise."[9]

A *value-based purpose* is defined by HHS as "(i) coordinating and managing the care of a target patient population; (ii) improving the quality of care for a target patient population; (iii) appropriately reducing the costs to, or growth in expenditures of, payors without reducing the quality of care for a target patient population; or (iv) transitioning from healthcare delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on quality of care and control of costs of care for a target patient population."[10]

The Stark Law exceptions involve three scenarios: full financial risk, meaningful downside financial risk and *no financial risk*.

- *Full financial risk* applies to remuneration paid under a value-based arrangement when the value-based enterprise is at full financial risk. Medically necessary items or services cannot be reduced or limited, nor can compensation be conditioned on referrals of patients who are not part of the target population.
- *Meaningful downside financial risk* applies if the physician is at meaningful downside financial risk for failure to achieve value-based purposes of the value-based enterprise during the entire duration of the

arrangement. Meaningful downside risk means that the physician is responsible to repay or forgo no less than 10% of the total value of remuneration the physician receives under the value-based arrangement.

- Regardless of the level of risk [if any] undertaken by the enterprise or any of its participants: The *no financial risk* exception includes similar restrictions on inducing the reduction or limitation of medically necessary services and referrals of patients who are not part of the target population. The arrangement must be in writing and include a description of the value-based activities to be undertaken, how these value-based activities are expected to further the value-based purposes of the enterprise, target patient population, type or nature of remuneration, payment methodology (which must be set in advance), and outcome measures against which the recipient of the remuneration is assessed.[11]

The exception also requires an annual monitoring to determine (1) whether the parties have furnished the required value-based activities; (2) whether and how continuation of the value-based activities are expected to further the value-based purpose of the enterprise; and (3) progress toward attainment of the outcome measures, if any.[12]

Many of the Stark Law exceptions require that: (1) the compensation arrangement is commercially reasonable; (2) the compensation paid under the arrangement is not determined in a manner that takes into account the volume or value of referrals (or, in some cases, other business generated between the parties); and/or (3) the amount of the compensation is fair market value.[13]

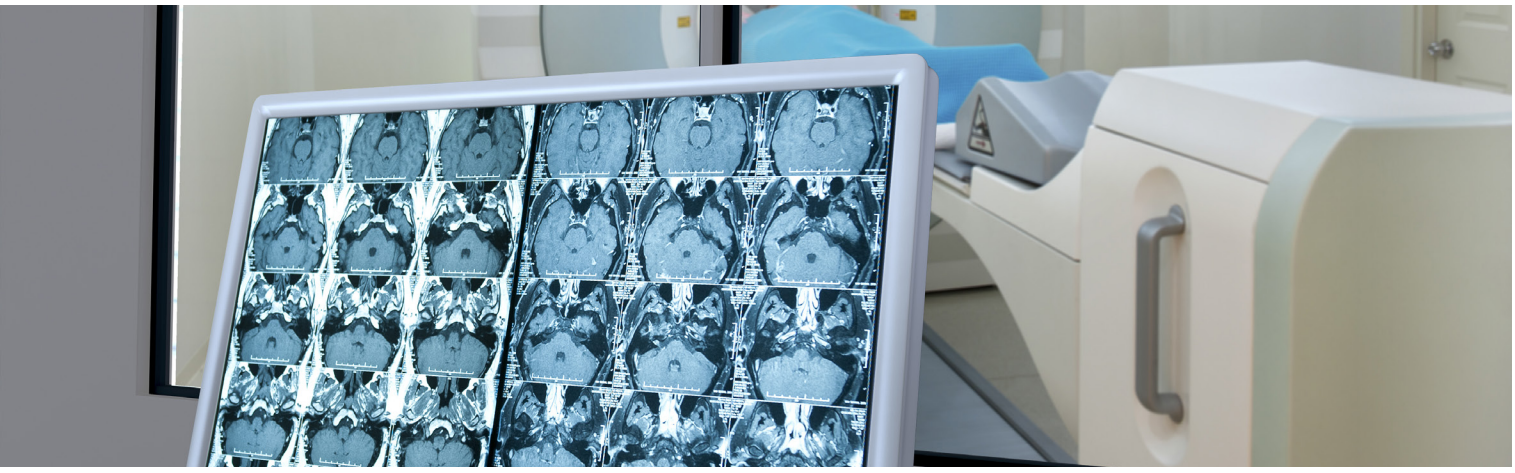
- *Commercially reasonable:* Furthers a legitimate business purpose of the parties to the arrangement and is sensible considering the characteristics of the parties, including their size, type, scope and specialty.[13]
- *Fair market value*: The value in an arm's length transaction, consistent with the compensation that would be paid at the time the parties enter into the service agreement 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.[13]

CMS states: "nothing in the final rule precludes the sharing of cost savings [gainsharing] and other entity specific savings programs, provided those programs are part of a value-based arrangement for value- based activities."[13]

Implications of changes

The goal of payment reform is to transition from fee-for-service to population-based capitation with providers at full risk for outcomes, i.e., quality, cost and satisfaction. Changes in the Stark Law and AKS exception allow for a variety of new relationships (arrangements) between entities and physicians collaborating to increase value.

A properly structured value-based arrangement (VBA) "can satisfy the new exception regardless of whether the compensation to be paid under the arrangement is consistent with fair market value or takes into account the volume or value of the physician's referrals to (or other business for) the DHS entity."[14] The arrangement may include an employment contract, shared savings agreement, medical directorship, call coverage, etc.



The VBA must, however, have at least one "anchor" value-based purpose: "(i) coordinating and managing the care of a target patient population; (ii) improving the quality of care for a target patient population; (iii) appropriately reducing the costs to, or growth in expenditures of, payors without reducing the quality of care for a target patient population; or (iv) transitioning from healthcare 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."[15]

The VBA must also, in writing, describe (1) the value-based activities to be undertaken by the arrangement; (2) how the activities are expected to further value-based purposes; (3) the target patient population; (4) the compensation; (5) the methodology used to determine the amount of compensation; (6) the attainment of outcome measures – if any – against which the physician will be measured.[3]

A value-based entity must comprise at least two participants collaborating to achieve at least one value-based purpose; it does not have to be the size of an Accountable Care Organization (ACO).[6] The target population can be selected based on a variety of "legitimate and verifiable" criteria as long as "cherry-picking" and "lemon-dropping" do not occur.[6]

Exceptions for a VBA associated with a value-based entity include full financial risk, meaningful downside risk (of at least 10% of physician remuneration) and no financial risk. Stark exceptions are inversely related to the degree of financial risk.

Bottom line

Despite more than a decade of experimentation with value-based payments, penetration rates remain low. Medicare, with 61.7 million beneficiaries, has been driving systemwide care transformation with its quality initiatives.[16]Approximately 10 million beneficiaries participate in ACOs;[17] 24.1 million beneficiaries are enrolled in Medicare Managed Care plans.[18] Quality initiatives are more limited with employer-sponsored insurance (175.1 million beneficiaries) and Medicaid (75.4 million beneficiaries).[19] Among physicians, only 6.2% of total cash compensation is for value-based incentive payments.[20]

Why the limited penetration rate of value-based initiatives among employer-sponsored insurance companies? Possible reasons are the geographic dispersion of employees covered in employer-sponsored plans (i.e., lack of concentrated risk pools) and limited understanding of value by employer benefit personnel.[21] Other reasons include difficulty collecting and reporting patient information (analytics), fears regarding (downside) financial risk, data exchange (interoperability) challenges, shifting policies and regulations, and lack of resources.[22] Different payers may utilize alternative compensation models, thereby creating (conflicting) challenges for providers.[23] A shift in culture is required.

Changes to the Stark Law and Anti-Kickback Statute do not necessarily alter the fundamental barriers to value-based market penetration. They do, however, allow for more flexibility in designing physician compensation plans under these arrangements, particularly for those taking full and meaningful (>10%) financial risk. Provider network resistance may lessen while care coordination increases. We project an incremental positive impact from the change.

Nonetheless, the changes do signal the government's ongoing interest in fostering and encouraging more value-based innovations. Consequently, providers — to the extent they aren't already — should (at least) focus on risk stratification to identify (and manage) the 5%-10% of the population accountable for 50%-66% of healthcare costs, enhance member access and engagement, and ensure high diagnostic-code accuracy as part of the revenue cycle to make certain that they are well positioned to participate in the evolving reimbursement environment."[24]

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