Stocking Stuffers: Small But Welcome Updates Arrive for Compensation Arrangements Under New Stark and Anti-Kickback Regulations?



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By Lori Beam

An early holiday present arrived for providers charged with establishing physician compensation arrangements. The Centers for Medicare & Medicaid Services (CMS) and the Office of Inspector General (OIG) for the Department of Health and Human Services released the new final rules with welcome updates for implementing compensation arrangements under the Physician Self-Referral Statute (the Stark Law) and the Anti-Kickback Statute (AKS).

At this season, they are more akin to stocking stuffers than a large gift but are still welcome.

Final Rules to AKS

The new final rules to the AKS offer providers greater flexibility in establishing compliant compensation arrangements by modifying the existing Personal Services and Management Contract. The revised safe harbor –

- Eliminates the requirement that the contract set the aggregate compensation in advance, now requiring only that it set the methodology for determining the compensation in advance.
- Removes the requirement that the contract specify the schedule, length and fee per interval under part-time, sporadic or periodic arrangements.

- Adds a new provision excluding from prohibited “remuneration” certain outcomes-based payments” for achieving measurable outcomes that improve patient or population health or appropriately reduce payor costs. The provision is helpful for protecting value-based arrangements and co-management agreements –
    - The outcome measures must be selected based on clinical evidence or credible medical support.
    - The methodology for determining the aggregate compensation over the term must be set in advance, commercially reasonable, consistent with fair market value and not determined in a manner that directly takes into account the volume or value of any referrals or business otherwise generated between the parties.
    - Payments for achieving measured outcomes may be –
        - a reward for achieving an outcome measure
        - a recoupment or reduction in payment for failing to achieve an outcome measure
        - or both of the above.
    - The agreement cannot limit any party’s ability to make decisions in the patients’ best interests or induce any party to reduce or limit medically necessary items or services.
    - The parties must regularly monitor and assess performance of each outcome measure and rebase outcome measures.
    - The arrangement must be in a writing signed by the parties and for a term of at least one year.
    - The safe harbor does not apply to payments made by certain entities such as pharmaceutical manufacturers/distributors/wholesalers, pharmacy benefit managers, laboratories and sellers of durable medical equipment.

Stark Law

New Limited Exception For Compensation at or Below $5,000

The new final rules to the Stark Law attempt to exempt certain arrangements CMS considers low risk of fraud and abuse. In addition to codifying certain previously proposed exceptions for administrative or operational errors, CMS added a new exception for cash or in-kind amounts at or less than $5,000 per calendar year paid by a provider of Designated Health Services (a DHS Entity) to a physician in exchange for items or services the physician provides.

- The items and services can include a physician’s lease or license of space or equipment so long as the arrangement doesn’t violate the prohibitions on per-click and percentage-based compensation formulas.
- In the case of services, they can be provided personally by the physician or through an employee, wholly owned entity or locum tenens physician, but not through an independent contractor.
- Like other compensation exceptions, the arrangement must be commercially reasonable and the compensation can’t exceed the fair market value of the furnished items or services or be determined in any manner that takes into account the volume or value of referrals.
- CMS will annually adjust the $5,000 amount for inflation.
- Where a provider has multiple arrangements with a physician –
    - The compensation paid to the same physician under an arrangement that meets one of the other exceptions to the Stark Law doesn’t count toward the $5,000 for purposes of meeting this new limited exception with respect to the second compensation arrangement.
    - Any two or more compensations arrangements that don’t meet any of the other Stark Law exceptions are treated as one arrangement for purposes of meeting the $5,000 limit under this new exception.
    - This exception can exempt a wide variety of compensation arrangements involving compensation not exceeding $5,000. It also can be used as a bridge up to $5,000 to correct

higher dollar arrangements when the parties temporarily fail to document an arrangement before it starts or the compensation arrangement is otherwise temporarily noncompliant with one of the other compensation arrangement exceptions to the Stark Law.

Revised Definitions and Clarifications Relating to Compensation

In a provider-friendly way, the new final rules also clarify key definitions used in various Stark Law exceptions applicable to compensation arrangements. For example, the new rules:

- Codify CMS's policies relating to the "volume or value of referrals or other business generated" standard used in a number of Stark Law exceptions to reduce confusion created by certain court cases by stating –
    - Compensation from a DHS Entity to a physician takes into account the "volume or value of referrals or other business generated" only if the *formula* used to calculate the compensation includes the physician's referrals *as a variable* resulting in an increase in compensation as referrals increase and a decrease in compensation as referrals decrease.
    - Productivity-based physician compensation formulas will not be deemed to "take into account" the volume or value of the physician's referrals solely because the hospital may bill for DHS each time the physician personally performs a service at the hospital.
- Reject the previously proposed definition of "commercially reasonable" that focused on whether it is a transaction entered into by entities of similar type and size, and instead define "commercially reasonable" as an arrangement that –
    - "furthers a legitimate business purpose *of the parties to the arrangement* and issensible, considering the characteristics of the parties, including their size, type, scope and specialty…"
    - "even if it does not result in profit for one or more of the parties."
- Recognize, in discussing is revised definitions of "fair market value and "general market value," that –
    - The fair market value of a transaction may not always align with valuation data compilations.
    - Physician salary schedules are "an appropriate starting point" in determining fair market value, although hospitals may appropriately need to pay more, such as based on a "compelling need," for certain physician services.
- Add flexibility to change compensation during the first year of the arrangement by –
    - Allowing changes in compensation so long as the modified arrangement meets one of the Stark Law exceptions from the date of the change and the modified compensation or formula is determined and set forth in writing before the rendering of the items and services for which the modified compensation applies.
    - Removing the requirement that the parties extend the new arrangement for at least one year from the date of the compensation amendment.

Gifts that Keep on Giving

All of these AKS and Stark Law changes are relatively small, but they are gifts that will keep on giving throughout the year and future years as hospital administrators, physicians and compliance officers strive to establish legally compliant compensation arrangements.

Happy holidays to all!

Watch for More Alerts

As mentioned in our Health Law Group's prior two client alerts, CMS and OIG adopted these final rules as part of their *Health and Human Services' Regulatory Sprint to Coordinated Care* initiative to remove

regulatory barriers that inhibit innovative arrangements for coordinating care. The regulations go into effect Jan. 19, 2021 – except for one Stark Law change that goes into effect Jan. 1, 2022.

We are breaking down the more than 1,600 pages of regulatory changes through a series of alerts you won't want to miss. Be on the lookout for additional articles.

This article is general in nature and does not constitute legal advice.

*Readers with legal questions should consult the author, Lori Beam (*lbeam@sb-kc.com*) or any other shareholders in Seigfreid Bingham's Health Law Group, including Mark Thompson, Mark Opara, Joseph Hiersteiner, Mark Gilgus, John Neyens, Heath Hoobing and John Fuchs, or your regular contact at Seigfreid Bingham at 816-421-4460.*