GW GARFUNKEL WILD, P.C. ATTORNEYS AT LAW Alert

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CMS ADOPTS IMPORTANT CHANGES TO THE STARK REGULATIONS

On December 2, 2020, the Centers for Medicare and Medicaid Services (CMS) issued a Final Rule that includes important changes to the federal physician self-referral law, commonly referred to as the "Stark Law." In general, the Stark Law prohibits a physician from making a referral for certain "designated health services" (DHS) to an entity with which the physician (or an immediate family member) has a financial arrangement, unless an exception applies. Concurrently with the Stark Law changes, the Office of Inspector General also issued new rules under the Federal Anti-kickback Statute, which will be addressed in separate client alerts.

As part of the Department of Health and Human Services' "Regulatory Sprint to Coordinated Care," and CMS' "Patients Over Paperwork" initiative, the Final Rule establishes a broad new exception to the Stark Law for value based arrangements, updated a number of existing exceptions, and perhaps most significantly for physician groups, clarified the permissible methods of distributing "overall profits" derived from DHS within a group practice. Recognizing that many groups will need time to modify their existing compensation arrangements to bring them into compliance, this portion of the Final Rule will not become effective until January 1, 2022. The remainder of the Final Rule will become effective on January 19, 2021.

Below is a brief summary of certain key provisions of the Final Rule.

CMS Clarifies Permissible Methods of Distributing DHS Profits in a Group Practice

One of the most significant aspects of the Final Rule is CMS' clarification of the manner in which a "group practice" – as defined in the Stark Law – may distribute overall profits derived from DHS within a group. Physician groups must qualify as a group practice in order to use the in-office ancillary services exception or the physician services exception, which both allow DHS to be ordered or referred within the group.

Prior to publication of the Final Rule, many physician groups distributed their overall profits from DHS on a "split-pool" basis, with one subgroup of five or more physicians receiving profits from one DHS service (*e.g.*, radiology), and another subgroup receiving profits from a different DHS service (*e.g.*, laboratory). CMS realized that its prior guidance may have been unclear. Accordingly, CMS has now clarified that the Stark Law will no longer permit overall DHS profits to be distributed in this manner.

Beginning on January 1, 2022, practices wishing to qualify as a "group practice" under the Stark Law must aggregate – before distribution in a Stark compliant manner – overall profits derived from DHS in one of two ways: (i) all profits from DHS of the entire group, or (ii) all profits from DHS of any subgroup consisting of five or more physicians. This means that overall profits derived from DHS may not be distributed (either among the entire group or in any pod of at least five physicians) on a service-by-service or split-pool basis (*e.g.*, allocating lab profits one way or to one group, and imaging profits another way or to another group).

To illustrate, CMS provides the following example. Assume a group practice comprised of 15 physicians furnishes three types of DHS: clinical laboratory services, diagnostic imaging services and radiation oncology services. Also assume that the group has divided its physicians into three pods of five physicians (pods A, B and C). Under the Final Rule, for each pod, the group practice must aggregate the profits from all of the DHS furnished by the group and referred by any of the five physicians in the pod. The group practice may distribute the overall profits from all the DHS of: (i) Pod A using one method (*e.g.*, per-capita), (ii) Pod B using a different method (*e.g.*, personal productivity), and (iii) Pod C using a third method that does not directly relate to the volume or value of the pod's physicians' referrals (or the methodology used for pod A or B). However, a group practice must utilize the same methodology for distributing overall DHS profits for every physician in each pod.

In addition, CMS clarified that there cannot be overlapping members in different pods for purposes of distributing overall profits derived from DHS. For example, a physician could not be in one pod of five for purposes of distributing lab profits, and a different pod of five for purposes of distributing radiology profits.

As noted previously, CMS recognizes that groups may need time to modify their compensation structures, and changes should only be made prospectively. As a result, CMS postponed the effective date of these modifications until January 1, 2022. Group practices that intend to comply with the changes should promptly review their distribution methodologies and address any modifications in a timely manner well ahead of the deadline.

Value Based Initiatives

The Final Rule adds three new Stark Law exceptions intended to address alternative payment methodologies, including: (1) value based arrangements with full financial risk; (2) value based arrangements with meaningful downside financial risk; and (3) any value based arrangements intended to encourage a focus on "patients over paperwork." These exceptions may be used whether or not the arrangement relates to care furnished to Medicare beneficiaries or other patients, and do not require that the remuneration be consistent with fair market value. As may be expected, the greater risk a provider or value based entity (VBE) assumes, the greater the protections and flexibility afforded under the Stark Law.[1]

- **Value Based Arrangements with Full Financial Risk Exception** – The full financial risk (FFR) exception applies when the VBE assumes full financial risk for the entire duration of the value based arrangement. However, the Final Rule permits up to a 12 month "pre-risk" timeframe. FFR arrangements often take the form of capitation payments per member per month, or a global budget payment for all patient care to the VBE.
- **Value Based Arrangements with "Meaningful" Downside Financial Risk Exception** – The meaningful downside financial risk (MDR) exception applies when the physician is responsible to repay or forgo at least 10% of the total value of the remuneration. Such "meaningful" downside risk must be borne by the physician for the entire duration of the agreement. Under the MDR exception, the focus is on the risk assumed by the individual physician in the value based arrangement. MDR arrangements often take the form of incentive payments, claw backs and reductions in compensation to providers.
- **Any Value Based Arrangements Exception** – A sort of catch all, the value based arrangements ("VBA") exception applies to any value based arrangements, regardless of the level of risk, that do not fall under the other two categories provided the VBA satisfies specific requirements. The VBA exception covers monetary and non-monetary remuneration.

Other Notable Changes to the Stark Law

- **Updated EHR Exception and New Cybersecurity Exception** – The Final Rule makes certain changes to the existing exception for electronic health records (EHR) items and services. The existing exception allows for the provision of nonmonetary remuneration (consisting of items and services in the form of software or information technology and training services) necessary and used predominantly to create, maintain, transmit, or receive EHR, if certain conditions are met. The exception was scheduled to expire on December 31, 2020, but the Final Rule eliminated that sunset provision. In addition, the rule adds an additional broad exception which allows for the provision of certain cybersecurity technology and related services[2].
- **Relaxation of Signed Writing Requirement** – CMS modified the special rules on compensation to clarify that exceptions requiring a signed written agreement (which includes most of the exceptions) may still be satisfied if the parties obtain the required writings or signatures within 90 consecutive calendar days immediately following the date on which the compensation arrangement became noncompliant (assuming all other requirements of the exception are met). CMS also added a requirement that the signature requirement may be met through an electronic or other signature that is valid under applicable federal or state law.
- **New Definition of Commercial Reasonableness; Modified Definition of Fair Market Value & General Market Value** – The Final Rule added a specific definition of "commercial reasonableness" to the Stark Law, which is a condition included in many exceptions. CMS now defines commercial reasonableness to mean that the

[1] The separate Final Rule issued by the federal Office of Inspector General also includes new "value-based" safe-harbors under the federal Anti-Kickback Statute (AKS). GW will be issuing two alerts on the new AKS Final Rule. The first alert can be viewed here. The second alert, which will address, among other things, the value-based safe harbors, will be issued in the coming days.

[2] The separate Final Rule issued by the federal Office of Inspector General also includes certain modifications to the existing EHR Safe Harbor and includes a new Safe Harbor addressing cybersecurity under the AKS. A discussion of these Safe Harbors can be viewed here.

particular arrangement furthers a legitimate business purpose of the parties and is sensible, considering the characteristics of the parties, including their size, type, scope and specialty. The definition specifically provides that an arrangement maybe commercially reasonable even if it does not result in profit for one or more of the parties.

The Final Rule also modified the definitions of "fair market value" (FMV) and "general market value" to better address different types of transactions. The revised definition of FMV now includes a general definition of that term, as well as specific definitions of FMV relating to the rental of both office space and equipment. The specific definitions of FMV also incorporate the term "general market value." The regulations also include separate definitions of general market value related to specific types of transactions, including assets sales, compensation, and the rental of equipment or office space.

- **Fixing Noncompliant Arrangements** – CMS recognizes that administrative or operational errors, or mistakes in implementation, may cause an otherwise properly structured arrangement to fall out of compliance temporarily. To address such situations, CMS clarified that entities are still allowed to submit claims and receive payment for DHS if - no later than 90 consecutive calendar days following the expiration or termination of a noncompliant arrangement - the parties reconcile any payment errors so that following reconciliation, the remuneration paid is consistent with the original terms and conditions of the arrangement.

- **Definition of DHS Modified** – The Final Rule modified the definition of DHS, stating that with respect to services furnished to inpatients by a hospital, a service is not considered DHS payable in whole or in part by Medicare if the furnishing of the service does not increase the amount of Medicare's payment to the hospital under certain listed "prospective payment systems." For example, if an inpatient was admitted under a specific DRG and while an inpatient, additional services were ordered (e.g., an x-ray), Medicare generally would not pay for the technical component of the x-ray because it is bundled into the existing DRG. Under the revised definition of DHS, the technical component of that additional x-ray service would not be considered DHS because it is not separately payable and therefore the referral for such service would not need to satisfy a separate Stark Law exception.

- **Fair Market Value Exception** – CMS modified the existing exception for fair market value compensation, extending its application to arrangements for office space and equipment. Prior to the Final Rule, the fair market value exception had expressly excluded application to leases for office space. As the exception does not require a one year term, it can be used for short term leases. In addition, the arrangement may be renewed any number of times provided that the original terms of the arrangement - and the compensation for the same items, services, office space or equipment – do not change.

- **New Exception for "Limited Remuneration to a Physician"** – CMS also added a new exception that permits the provision of limited payments by an entity to a physician for items or services provided by the physician (or employees of the physician), if certain requirements are met. The exception is limited to amounts not to exceed $5,000 (adjusted annually) per calendar year.

The above is intended as a brief summary of certain notable aspects of the Final Rule. The regulations themselves are extremely complex, detailed and include many additional provisions and requirements that are too lengthy to summarize here. The Stark Law should always be considered with the help of qualified legal counsel.

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Should you have any questions regarding the above, please contact the Garfunkel Wild attorney with whom you regularly work, or contact us at info@garfunkelwild.com. Please check our website for separate legal alerts about the Final Rule related to the federal Anti-Kickback Statute.

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