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

December 2020

OIG ISSUES IMPORTANT NEW AND REVISED SAFE HARBORS Under The Federal Anti-Kickback Statute – Part 2

As we previously reported, the United States Department of Health and Human Services Office of Inspector General ("OIG") recently issued an important final rule (the "Final Rule") that makes significant changes to existing "Safe Harbors" under the Federal Anti-kickback Statue ("AKS") and that adds new Safe Harbors that provide protection from AKS sanctions for certain types of arrangements. The Final Rule takes effect on January 19, 2021.[1]

This Alert is the second of two discussing the Final Rule. The first Alert may be found here. In this Alert, we focus on the Final Rule's new "value-based" Safe Harbors as well as new Safe Harbors for CMS-sponsored model arrangements and patient incentives, and for Accountable Care Organization ("ACO") Beneficiary Incentive Programs. We also address changes made by a separate OIG rule to the "discounts" Safe Harbor, including the creation of two new Safe Harbors.

Additional New and Revised Safe Harbors in the Final Rule

A. New Value-Based Safe Harbors. One of the most significant changes in the Final Rule is the creation of a series of "value-based" Safe Harbors. These Safe Harbors are designed to help remove regulatory obstacles and encourage participation in value-based payment arrangements, as part of the shift from a volume-driven health care system to one based on value and outcomes. The value-based Safe Harbors are detailed and complex. Throughout, they include a myriad of terms and concepts that are integral to understanding and complying with the respective Safe Harbor requirements. These include definitions for what constitutes a "value-based activity," a "value-based arrangement," and a "value-based" purpose"; which types of entities qualify as a "value-based enterprise" ("VBE") and "VBE participant"; and the definition of what makes up a "target patient population". The Final Rule also includes a list of entities that are considered ineligible for protection under these Safe Harbors.[2]

Three of the new value-based Safe Harbors focus on the amount of risk assumed at the VBE level:

1. Value-Based Arrangements with Full Financial Risk. This new Safe Harbor protects both monetary and in-kind remuneration when the VBE assumes full financial risk (defined to mean the VBE is financially responsible on a prospective basis for the cost of all items and services covered by the applicable payor for each patient in the target patient population of the value-based arrangement for a term of at least 1 year) through a written contract or value-based arrangement. The value-based arrangement must be in a writing containing all material terms and the payor must reimburse the VBE on a prospective basis.

2. Value-Based Arrangements with Substantial Downside Financial Risk. This new Safe Harbor protects both monetary and in-kind remuneration when a VBE takes on a "meaningful share" of "substantial downside" risk. OIG's Final Rule provides that a VBE participant must share in at least 5% of the total losses and savings under the value-based arrangement to qualify as a "meaningful share" (or otherwise meet the definition provided in the regulation). Further, OIG provides a risk threshold of between 20% to 30% for defining "substantial downside" depending on which of four methodologies (episodic payment methodology, VBE partial capitation methodology, shared savings and losses methodology and population-based payment methodology) is used to calculate the

[1] Concurrently with the Final Rule, the Centers for Medicare and Medicaid Services ("CMS") separately issued significant new rules under the Federal "Stark Law". While there are often Stark Law exceptions that are similar to the AKS Safe Harbors, they are not necessarily the same. Please see our separate alert discussing the new changes to the Stark Law regulations, which is available here.

[2] This includes pharmaceutical manufacturers, wholesalers and distributors; pharmacy benefit managers; laboratory companies; medical device manufacturers, distributors and wholesalers; devices or medical supplies and durable medical equipment ("DMEPOS") companies; and compounding pharmacies (but see the limited exception for DMEPOS discussed below).

"substantial downside." The VBE must assume risk on a prospective basis for one year, and the value-based arrangement must be in a writing containing all material terms. In addition, the remuneration must be directly connected with at least one VBE purpose.

3. Care Coordination Arrangements to Improve Quality, Health Outcomes and Efficiency. This new Safe Harbor protects only in-kind remuneration exchanged between a VBE and VBE participants or among VBE participants if used predominantly to engage in value-based activities directly related to care coordination and management of care for the target patient population. This Safe Harbor assumes that there is no risk or less than "substantial downside" risk in the value-based arrangement. The Final Rule imposes a contribution requirement of 15% of either: (1) the remuneration; or (2) the fair market value of the remuneration. Value-based arrangements under this Safe Harbor must be in a writing that describes the value-based activities, the term and target patient population, specific outcome measures and either the fair market value of the remuneration or the cost of the remuneration and the percentage and amount contributed by the recipient of the remuneration. The value-based arrangement must contain an annual monitoring requirement requiring the VBE to assess the coordination and management of care for the target patient population. Any deficiencies identified must be addressed by either terminating the value-based arrangement within 60 days or making a plan to remedy such deficiencies within 120 days. Unlike the other value-based Safe Harbors referenced above, this Safe Harbor may be available to VBE participants that are manufacturers of medical devices or supplies that may qualify as "limited technology participants." [3]

B. Other New Safe Harbors in the Final Rule

In addition to the above Safe Harbors, the Final Rule has a number of other new Safe Harbors, including the following:[4]

1. Arrangements for Patient Engagement and Support to Improve Quality, Health Outcomes and Efficiency. This new Safe Harbor allows a VBE participant to provide patient engagement tools and supports to a patient in the target population of a value-based agreement (as long as the VBE is a participant to the agreement), provided (as is the case with all Safe Harbors) that all other elements to the Safe Harbor are met.[5] While the Final Rule does not define a patient engagement tool or support, it does set forth certain specific requirements for the patient engagement tool or support including, but not limited to, that the item: (a) must be provided directly to the patient (with limited exceptions for family, caregivers, or other individual acting on the patient's behalf) by a VBE participant (or eligible agent); (b) must advance one or more of the goals set forth in the regulation, *e.g.*, patient adherence to treatment or medication regimens; and (c) must be an in-kind item, good or service that has a direct connection to the coordination and management of care of the target population. This Safe Harbor caps the amount of tools or supports a VBE participant may provide to a patient at an aggregate retail value of $500 per year (adjusted annually for inflation). In addition, the VBE participant cannot exchange or use the patient engagement tools or supports to market other reimbursable items or services or for patient recruitment purposes. The tool or support must not result in medically unnecessary or inappropriate items or services reimbursed by a Federal health care program, and must be recommended by the patient's licensed health care professional. Further, a patient's insurance coverage cannot be considered when determining the availability of a tool or

---

[3] This is in contrast to the new Federal Stark Law regulations, which do not exclude specific provider types from the Stark Law's value-based exceptions (see here).

[4] Please also see our earlier Alert on the Final Rule, which may be accessed here.

[5] This Safe Harbor generally includes the list of ineligible providers referenced above with a few changes including: manufacturers of devices and medical supplies are only eligible for protection to the extent they provide digital health technology (as defined). Companies that sell or rent DMEPOS (other than a pharmacy, a manufacturer of a device or medical supply, or a physician, provider, or other entity that primarily furnishes services) are excluded without exception. Medical device manufacturers, distributors, or wholesalers with ownership or investment interests held by physicians are also ineligible. There are also limitations on who may fund or contribute a patient engagement tool or support.

support. There is also a record-keeping requirement under this Safe Harbor: the VBE is required to retain documentation sufficient to establish compliance for 6 years.

2. CMS-Sponsored Model Arrangements and CMS-Sponsored Model Patient Incentives. The Final Rule also creates a new Safe Harbor for certain CMS-sponsored models and CMS-sponsored model patient incentives under the Center for Medicare and Medicaid Innovation (the Innovation Center) and the Medicare Shared Savings Program. The intent of this new Safe Harbor is to significantly reduce the need for the OIG to issue model-specific fraud and abuse waivers. The extent to which this Safe Harbor is available for new and existing CMS-sponsored models is determined by CMS. If CMS determines that the Safe Harbor is available for a given CMS-sponsored model, certain exchanges of value between or among CMS-sponsored model parties under a CMS-sponsored arrangement would be protected if the conditions of the Safe Harbor are met. With respect to patient incentives, in order to qualify for Safe Harbor protection, the incentive must have a direct connection to the patient's health care unless the underlying CMS-sponsored model participation documentation sets forth a different standard. If CMS determines the Safe Harbor is available for a specific model (existing or new), CMS will issue a public notice or notices to individual participants.

3. ACO Beneficiary Incentive Program. This new Safe Harbor protects incentive payments made by an ACO to an assigned beneficiary who receives qualifying primary care services from providers in the ACO, if all of the requirements set forth under section 1899(m) of the Social Security Act – related to both the ACO Beneficiary Incentive Programs and incentive payments made pursuant to those programs – are met.

C. Recent OIG Rule Regarding Changes to the Discounts Safe Harbor and Creation of Two New Safe Harbors. In a separate final rule announced on November 30, 2020, the OIG made changes to the "Discounts" Safe Harbor as it relates to rebates from drug manufacturers to Medicare Part D plans, to address its concern that the current rebate-based system may be increasing financial burdens for certain Medicare beneficiaries. Effective January 1, 2022, reductions in price in connection with the sale or purchase of prescription pharmaceutical drugs from manufacturers to Medicare Part D plan sponsors, either directly or through Pharmacy Benefit Managers ("PBMs"), do not qualify for protection under the Discounts Safe Harbor. In the same rule, the OIG created two new related Safe Harbors – the Point-of-Sale Reductions in Price for Prescription Pharmaceutical Products Safe Harbor, and the PBM Service Fees Safe Harbor, both of which become effective January 29, 2021.

The new and revised Safe Harbors under the AKS are both significant and complex. When considering whether or not the AKS or any of its Safe Harbors apply to an existing or contemplated arrangement, experienced health care counsel should be consulted.

* * * * *

Should you have any questions on how the revised or new Safe Harbors might impact either your existing arrangements or any potential new arrangements you may be considering, please contact the Garfunkel Wild attorney with whom you regularly work, or contact us at info@garfunkelwild.com. Please also check our website for our prior Alert on the OIG's Final Rule announcing new and revised Safe Harbors (here), as well as our Alert discussing CMS' important new changes to the Federal Stark Law regulations (here).

Contact Information:

111 Great Neck Road	411 Hackensack Avenue	350 Bedford Street	677 Broadway
Great Neck, NY 11021	Hackensack, NJ 07601	Stamford, CT 06901	Albany, NY 12207
516.393.2200	201.883.1030	203.316.0483	518.242.7582