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

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OIG ISSUES IMPORTANT NEW AND REVISED SAFE HARBORS Under The Federal Anti-Kickback Statute – Part 1

The United States Department of Health and Human Services ("HHS"), 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 also includes a new regulatory exception to the definition of "remuneration" under the Federal Civil Monetary Penalties ("CMP") law for certain telehealth technologies provided to an individual with end-stage renal disease ("ESRD") who is receiving home dialysis paid for under Medicare Part B. The Final Rule takes effect on January 19, 2021.[1]

The Final Rule was issued as part of HHS's "Regulatory Sprint to Coordinated Care." The goals of the Regulatory Sprint are to reduce regulatory barriers to care coordination, and to accelerate the transformation of the health care system from one that is based on a volume-driven payment system to one that focuses on value-based payments and the promotion of care coordination.

The changes in the Final Rule are significant for both existing and contemplated arrangements, and present both challenges and new opportunities for those in the health care industry. Now is a good time for you to assess the impact of the Final Rule on both your current relationships and on relationships that you may be contemplating entering into in the future.

A. The AKS. The AKS is a Federal law that makes it a crime to knowingly and willfully offer, pay, solicit, or receive remuneration to induce or reward, among other things, the referral of business reimbursable under any Federal health care program, including Medicare and Medicaid. An AKS violation is a felony offense, punishable by fines of up to $100,000 and up to 10 years in jail. In addition, an AKS violation may also result in civil monetary penalties, program exclusion and/or Federal False Claims Act liability. Because of the broad reach of the AKS, the OIG has promulgated regulations, known as "Safe Harbors," regarding certain payment and business practices that would not be subject to sanctions under the AKS, even though they otherwise may be capable of inducing referrals of business for which payment may be made under a Federal health care program.

B. Changes to Existing Safe Harbors under the Final Rule. Below we summarize some of the more significant changes to existing Safe Harbors under the Final Rule, as well as the addition of a new Safe Harbor protecting the provision of certain cybersecurity technology and related services. Please note that this Alert does not

[1] This Alert is the first of two discussing the Final Rule and other recent regulatory rulemaking relating to the AKS. Specifically, this Alert focuses on certain important changes to existing Safe Harbors, as well as the creation of a new Safe Harbor for cybersecurity technology and related services. It also addresses the new regulatory exception to the definition of "remuneration" under the CMP rules for certain telehealth technologies provided to an individual with ESRD who is receiving home dialysis paid for under Medicare Part B. An ensuing Alert will address the new the "value based" Safe Harbors in the Final Rule, other significant additions to the Safe Harbors made by the Final Rule, as well as other AKS-related rules that have been recently revised. 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.

address each of the requirements of the Safe Harbors discussed below. Importantly, for a Safe Harbor to apply, all of the requirements of the Safe Harbor must be squarely met.

Some of the key changes to existing Safe Harbors made by the Final Rule include the following:

1. **Personal Services and Management Contracts and Outcomes-Based Payment Arrangements.** The "personal services and management contracts" Safe Harbor was re-named as the "personal services and management contracts and outcomes-based payment arrangements" Safe Harbor. Important changes to this Safe Harbor include: (a) eliminating the requirement that periodic, sporadic or part-time agreements must specify the exact schedule of the intervals involved, their precise length and the exact charge for such intervals, (b) eliminating the requirement that the aggregate compensation paid to the agent over the term of the agreement be set in advance; instead, the Safe Harbor now requires that the *methodology* for determining the agent's compensation over the term of the agreement be set in advance, and (c) adding an entirely new section to protect certain "outcomes-based payments" (as defined in the Safe Harbor) from a principal to an agent that meet 8 specific requirements set out in the Safe Harbor. These changes will potentially make it easier to fit squarely within this Safe Harbor for a variety of arrangements (*e.g.*, marketing arrangements), and open up new opportunities for certain "outcomes-based" payment agreements.

2. **Local Transportation.** The "local transportation" Safe Harbor was amended by the Final Rule to, among other things, expand the mileage restriction for eligible entities providing free or discounted local transportation to Federal health care program beneficiaries who reside in a rural area to within 75 miles (increased from 50 miles) of the health care provider or supplier to or from which the patient would be transported. Additionally, in a significant change that could impact existing hospital free or discounted local transportation policies, the Safe Harbor was also amended to eliminate any mileage limitation on free or discounted local transportation made available to a Federal health care program beneficiary if the patient is discharged from an inpatient facility following inpatient admission or released from a hospital after being placed in observation status for at least 24 hours and transported to the patient's residence or another residence of the patient's choice.

3. **Electronic health records items and services.** The Final Rule also amends the Safe Harbor for electronic records items and services in certain respects. Here, too, the changes made by the Final Rule may make it easier to qualify for this Safe Harbor. For example, in addition to creating a new Safe Harbor for cybersecurity technology and related services (see below), cybersecurity software and services are now specified as eligible for protection under this Safe Harbor. Moreover, the Final Rule eliminates: (a) the requirement that the donor (or any person on the donor's behalf) not take any action to limit or restrict the use, compatibility or interoperability of the items or services with other electronic prescribing or electronic health records systems (including, but not limited to, health information technology applications, products or services), (b) the requirement that the donor not have actual knowledge of, or act in reckless disregard or deliberate ignorance of, the fact the beneficiary possesses or has obtained items or services equivalent to those provided by the donor, and (c) the "sunset" provision that had previously been built into the regulation. The Final Rule also clarifies when the recipient of a donation must pay their cost-sharing amount (15%).

4. **Warranties.** Among other things, the Final Rule (a) expands the "warranties" Safe Harbor to include warranty arrangements for bundled items and services, if the warranty covers at least one item; (b) provides that if a manufacturer or supplier offers a warranty for more than one item or one or more items and related services, the Federally reimbursable items and services subject to the warranty must be reimbursed by the same Federal health care program and in the same payment; (c) requires that the

manufacturer or supplier must not condition a warranty on a buyer's exclusive use of, or minimum purchase of, any of the manufacturer's or supplier's items or services; and (d) updates the definition of what qualifies as a "warranty," and makes a number of other clarifications to the Safe Harbor's requirements.

C. **New Safe Harbor for Cybersecurity Technology and Related Services.** Among the new Safe Harbors in the Final Rule is one for cybersecurity technology and related services. Specifically, the Final Rule creates a Safe Harbor to protect nonmonetary remuneration consisting of cybersecurity technology and services that is necessary and used predominantly to implement, maintain or reestablish effective cybersecurity, provided that four conditions are met. "Cybersecurity" under the new Safe Harbor means the process of protecting information by preventing, detecting and responding to cyberattacks. "Technology" means any software or other types of information technology. The four requirements to meet this new Safe Harbor are that: (a) the donor may not (i) directly take into account the volume or value of referrals or other business generated between the parties when determining the eligibility of a potential recipient for the technology services, or the amount or nature of the technology or services to be donated, or (ii) condition the donation of technology or services, or the amount or nature of the technology or services to be donated, on future referrals, (b) neither the recipient nor the recipient's practice (or any affiliated individual or entity) may make the receipt of technology or services, or the amount or nature of the technology or services, a condition of doing business with the donor, (c) a general description of the technology and services being provided and the amount of the recipient's contribution, if any, must be set forth in a writing signed by the parties, and (d) the donor may not shift the costs of the technology or services to any Federal health care program.

D. **Telehealth Technologies Provided to Medicare Part B ESRD Beneficiaries Receiving Home Dialysis.** In addition to changes and additions to the AKS Safe Harbors, the Final Rule also includes a change to OIG's regulations affecting the "beneficiary inducements" provision to the CMP. Specifically, based on the Bipartisan Budget Act of 2018, the Final Rule codifies a new regulatory exception to OIG's CMP rules that excludes from the definition of "remuneration" the provision of telehealth technologies by a provider of services, physician or renal dialysis facility to an individual with ESRD receiving home dialysis for which Medicare Part B pays, if all of the following conditions are met: (a) the telehealth technologies are furnished to the individual by the provider of services, physician or renal dialysis facility that is currently providing the in-home dialysis, telehealth services or other ESRD-related care to the individual, or has been selected or contacted by the individual to schedule an appointment or provide services, (b) the telehealth technologies are not offered as part of any advertisement or solicitation, and (c) the telehealth technologies are provided for the purpose of furnishing telehealth services related to the individual's ESRD.

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Should you have any questions on how the revised or new Safe Harbors might impact either your existing arrangements or any potential new arrangements, please contact the Garfunkel Wild attorney with whom you regularly work, or contact us at info@garfunkelwild.com. Please also check our website for a separate alert about CMS' important new changes to the Federal Stark Law regulations.

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