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Client Alert

OCTOBER 17, 2019

FDA AND LIFE SCIENCES

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HHS Issues Proposed Rule to Update Anti-Kickback Statute Safe Harbors – What Does it Mean for Life Sciences Companies?

HHS' Proposals are Designed to Promote Patient Care Coordination, Management, and Efficiencies, and Include Several Points of Interest for Pharmaceutical and Medical Device Manufacturers

In today's *Federal Register*, the Department of Health and Human Services (HHS or the Department) released a Proposed Rule that would modify several existing safe harbors under the Anti-Kickback Statute (AKS) and create a host of new safe harbor protections. There are a number of aspects of this Proposed Rule that, if implemented, would impact the life sciences industry. The Department's proposed updates to the personal services and warranties safe harbors will be of specific interest to pharmaceutical and medical device manufacturers. Other proposals – including three newly proposed safe harbors for value-based arrangements, as well as newly proposed safe harbors relating to patient engagement tools, payment models sponsored by the Centers for Medicare and Medicaid Services (CMS), and cybersecurity technology and services – may be less likely to have a significant direct impact on life sciences companies, but offer helpful insights into HHS's current thinking around its efforts to modernize the AKS safe harbors, including possible plans for future rulemakings with proposals more focused on life sciences entities.

Comments on the Proposed Rule are due seventy-five (75) days after publication – by December 31, 2019.

MODERNIZING SAFE HARBORS TO ENCOURAGE IMPROVED COSTS AND PATIENT OUTCOMES

The preamble to the Proposed Rule notes that HHS intends to modify existing AKS safe harbors and add new safe harbors and a new civil money penalty (CMP) law exception to remove potential barriers to more

effective coordination and management of patient care and delivery of value-based care that improves quality of care, health outcomes, and efficiency. As discussed in more detail below, unfortunately many of the proposed changes that effectuate this mandate do not apply to many life sciences entities (and only direct benefit health care providers). The Proposed Rule comes as part of HHS's Regulatory Sprint to Coordinated Care (Regulatory Sprint) initiative (which seeks to reduce regulatory burden and incentivize coordinated care), and was crafted based, in part, on the 359 stakeholder comments that the Department received in response to its August 27, 2018 Request for Information.

(CMS has proceeded similarly with its efforts to modernize the Stark Law exceptions, issuing a Request for Information in June 2018 and a Proposed Rule in October 2019 that would modify the Stark Law exceptions.)

PROPOSED MODIFICATIONS TO EXISTING SAFE HARBORS

The Proposed Rule includes notable amendments to several existing safe harbors applicable to the life sciences industry.

- **Personal Services**. The Proposed Rule seeks to modify the existing personal services safe harbor to afford additional flexibility in achieving compliance. Specifically, the Proposed Rule would remove the current requirement that the aggregate compensation be set forth in advance for the term of the agreement. Instead, it would require the parties only to determine the compensation methodology upfront, in advance of the first payment under the agreement. In addition, the Proposed Rule seeks to delete the requirement that arrangements that contemplate service on a periodic, sporadic or part-time basis specify the exact schedule, length, and charge for such intervals.

  Since these two requirements of the safe harbor have been the two of the most challenging to satisfy, the revisions would likely shelter a much wider range of arrangements, and could offer meaningful new protection for manufacturers and their service providers. For example, agreements between manufacturers and health care professionals (HCPs) for as-needed consulting or speaking services would be more likely to meet the revised personal services safe harbor, provided that compensation is fair market value and the other requirements are met. Additionally, arrangements with independent sales agents (which do not qualify for the employee safe harbor) may be able to gain protection, presuming that the other safe harbor elements also would be satisfied (including that compensation not be determined in a manner that takes into account the volume or value of business generated).

  We note, however, that perhaps the most progressive proposed modification to the safe harbor -- which would protect "outcomes-based payments" that reward a contractor for improving patient or population health or achieving one or more outcome measures that reduce payer costs while improving care -- would not be extended to life sciences entities. Specifically, any payments made "directly or indirectly, by a pharmaceutical manufacturer; a manufacturer, distributor, or supplier of durable medical equipment, prosthetics or supplies (DMEPOS); or a laboratory" would be excluded from the new provision of the safe harbor protecting outcomes-based payments. This exclusion reinforces a theme echoed throughout the Proposed Rule: OIG remains suspect of manufacturer-industry relationships (even if those relationships are designed to achieve better health outcomes), citing both its enforcement and oversight experience as a basis for concern that manufacturers (and like entities) are heavily dependent upon HCP prescriptions and referrals, and therefore might use outcomes-based payments to market their products to providers and patients.

- **Warranties**. The Proposed Rule would expand the current warranties safe harbor to broaden the scope of the protection to warranties covering "one or more items and services." This new protection would mean that manufacturers could provide warranty protection across an entire bundled sale (rather than separate warranty protections to each individual item within the bundle), including both items and services. The potential protection of services (*e.g.*, repair and educational services) as part of the warranty could greatly expand how manufacturers approach warranties and the types of items and services that would be included under a warranty. The preamble to

the Proposed Rule, however, HHS cautions that the modified safe harbor would not protect free or reduced-priced items or services (*e.g.* laboratory tests) that have an independent value and that are provided as part of or ancillary to a bundled warranty agreement.

The Proposed Rule also adds additional requirements to meet the safe harbor, including that, if the warranty applied to multiple items and related services, then the federally reimbursable items and services subject to the warranty must be reimbursed by the same federal healthcare program and in the "same federal healthcare program payment." The warranty must also not be conditioned on the buyer's exclusive use of, or a minimum purchase of, any of the manufacturer's items or services. HHS provided several examples of what it would consider the same federal healthcare program payment, including payments under the same Part A Severity-Diagnosis Related Group (MS-DRG), Medicare Part B ambulatory payment classification, or Medicaid managed care payment. This condition is generally similar to a provision in the AKS discount safe harbor, and would limit the scope of the expanded warranty safe harbor in the same way the discount safe harbor limits the types of bundled sales that qualify for safe harbor protection.

Notably, the Proposed Rule would cap the amount a manufacturer or supplier could pay a customer under the safe harbor to the cost of the items and services subject to the warranty. HHS believes that this cap is a necessary safeguard to protect against companies attempting to improperly induce customers through excessive warranty payments.

Finally, the proposed modification expands the definition of "warranty" to also include written affirmations or promises that the company's quality or workmanship is defect free or will meet a specified level of performance over a specified period of time, and that the company will refund, repair, or replace any item or bundle of items that does not meet the bargained for specifications. Importantly, HHS notes that it interprets this protection to apply to arrangements containing clinical outcome guarantees.

- **Electronic Health Records**. The Proposed Rule seeks to expand what is excluded from "remuneration" under this safe harbor to explicitly include "certain cybersecurity software and services." The Proposed Rule also updates the safe harbor's provisions regarding interoperability and removes the sunset date (December 21, 2021) for the safe harbor. HHS highlighted the close connection between this proposed modification and a proposed new cybersecurity safe harbor (see below) – noting that the Department wanted to make clear that an entity donating electronic health records software and providing training and other related services may also donate related cybersecurity software and services to protect the electronic health records. The emphasis on cybersecurity is part of a broader government directive to better protect all kinds of digital information. The government recognizes the value and potential risk of digital information in the life sciences sector and is taking affirmative steps to strengthen cybersecurity. The proposed safe harbor coupled with this proposed modification creates an opportunity for life sciences companies to commit renewed or additional focus on cybersecurity.

PROPOSED NEW SAFE HARBORS

The Proposed Rule also would add several new safe harbors designed to enhance efficiency in the healthcare industry and improve patient care and outcomes. As noted below, many of the proposed safe harbors would not extend to most life sciences entities. HHS notes, however, in the preamble to the Proposed Rule, that the Department is interested in working with industry in these same areas. Despite HHS still being skeptical of arrangements between industry and healthcare professionals/entities, HHS notes repeatedly that it is interested in continuing to work with industry with regard to value-based relationships and finding ways to enhance patient care (and that this continued work could lead to future safe harbor protections).

- **Value-Based Arrangements**. The Proposed Rule introduces three potential AKS safe harbors for value-based arrangements for health care providers and health plans. Notably, the proposed value-based safe harbors expressly exclude from the definition of "value-based entity participant", and therefore from the proposed safe harbor protections, pharmaceutical manufacturers, DMEPOS manufacturers, distributors and suppliers, and laboratories. (These are the same entities excluded from significant revisions to the personal services safe harbor, as described above).

  That said, the proposed exclusions from "value-based entity participant" does not include all medical device manufacturers. HHS created the exclusion because it is "concerned that some companies within these types of entities, which are heavily dependent upon practitioner prescriptions and referrals, might misuse the proposed safe harbors primarily as a means of offering remuneration to practitioners and patients to market their products, rather than as a means to create value for patients and payors. . . ." (Proposed Rule pp. 53-54). HHS seeks comments on the proposed exclusion and whether the Department should also exclude from the definition and resulting protections all other medical device manufacturers, wholesalers, and distributors and pharmacy benefits managers (PBMs). The Department recognized that future rulemaking may be necessary to address value-based arrangements with pharmaceutical and/or medical device manufacturers.

  The obligations to meet each safe harbor varies based on the amount or risk borne by the parties, with more stringent requirements being applied to the lower financial risk scenarios. While these proposed safe harbors would not apply to most pharmaceutical and medical device manufacturer arrangements, the requirements may be helpful for industry to better understand the parameters being sought by HHS with respect to any potential protections and/or to develop comments to HHS.

  - **Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency.** This proposed safe harbor would protect *in-kind* remuneration exchanged between qualifying "value-based entity" (VBE) participants within value-based arrangements that squarely satisfy all of the proposed safe harbor's requirements, including, but not limited to: (1) the parties to a value-based arrangement must establish one or more specific evidence-based, valid outcome measures that the parties reasonably anticipate will advance the coordination and management of care of the target patient population; (2) the value-based arrangement is commercially reasonable and set forth in writing; (3) the remuneration provided by, or shared among, VBE participants be used primarily to engage in value-based activities that are directly connected to the coordination and management of care of the target patient population; (4) the remuneration does not induce the parties to furnish medically unnecessary items or services or reduce or limit medically necessary items or services furnished to any patient; and (5) the value-based arrangement has a direct connection to the coordination and management of care for the target patient population. Unlike the other proposed value-based safe harbors, discussed below, this proposed safe harbor does not require the parties to bear downside financial risk; accordingly, it includes the most proposed requirements.
  - **Value-Based Arrangements with Substantial Downside Financial Risk.** This proposed safe harbor would protect both monetary and in-kind remuneration and provides parties with greater flexibility "than the safe harbor for care coordination arrangements in recognition of the VBE's assumption of substantial downside financial risk."[1] HHS provided examples of arrangements to which this proposed safe harbor may apply, including an arrangement between an accountable care organization that is a VBE and a network provider to share savings and losses earned or owed by the accountable care organization, or between a VBE that has contracted with a payor for an episodic payment and a hospital and post-acute care provider that would be coordinating care for patients under the episodic payment.

  - **Value-Based Arrangements with Full Financial Risk.** Finally, this proposed safe harbor would allow the parties the most flexibility – again in recognition of the increased financial burden assumed by the parties. The Proposed Rule states that a VBE would be at "full financial risk" under arrangements in which the VBE would be "financially responsible for the cost of all items and services covered by the applicable payor for each patient in the target patient population and is prospectively paid by the applicable payor." HHS believes that this proposed safe harbor would allow parties the most ability to innovate with regard to their value-based, coordinated care arrangements.

- **Patient Engagement Tools.** The Proposed Rule seeks to create a safe harbor to protect certain arrangements for patient engagement tools designed to improve quality, health outcomes, and efficiency furnished by VBE participants. HHS noted that currently the AKS and CMP law may present barriers to providers offering patient engagement tools that benefit patients and improve quality, health outcomes, and efficiency through adherence to care protocols. The proposed safe harbor would exclude from the definition of "remuneration" that would implicate the AKS in-kind patient engagement tools or supports furnished directly by a VBE participant to a patient in a target patient population. The in-kind tools or support would also need to be directly connected to the coordination and management of care. Note that, since many life sciences manufacturers and entities are excluded from the proposed definition of VBE participant, this proposed safe harbor also would have limited application for the life sciences industry; however, there are strong arguments that this safe harbor should apply to all life sciences entities. This may be a prime target for comments by pharmaceutical and medical device manufacturers.
- **CMS-Sponsored Models**. The Proposed Rule would create a safe harbor to: (i) permit remuneration between and among parties to arrangements under a model or other initiative being tested or expanded by the Center for Medicare and Medicaid Innovation (the Innovation Center) or the Medicare Shared Savings Program (CMS-sponsored models) and (ii) permit incentives and supports provided by CMS model participants and their agents under a CMS-sponsored model to patients covered by the CMS-sponsored model. HHS notes that the goal of this proposed safe harbor is to standardize and simplify AKS compliance for CMS-sponsored model participants in certain models by applying uniform conditions across all CMS-sponsored models. This proposed safe harbor would make it easier for CMS to set up pilots and study projects, including with manufacturers, as OIG would no longer need to be consulted as long as the very limited safe harbor requirements could be met.
- **Cybersecurity Technology and Services**. The Proposed Rule seeks to create a safe harbor to protect donations of certain cybersecurity technology and related services. HHS believes that this proposed safe harbor could help improve the healthcare industry's cybersecurity by promoting increased security for interconnected and interoperable healthcare information technology systems without protecting arrangements that either serve as marketing platforms or inappropriately influence clinical decision-making. This change would allow entities to donate cybersecurity software to customers or referrals sources. CMS is proposing a similar exception to the Stark Law. This safe harbor would not be restricted to VBE participants and could be utilized by manufacturers and others.

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The Proposed Rule offers a number of key opportunities for life sciences industry stakeholders to expand regulatory protections for certain key types of remunerative engagements and activities. King & Spalding's fraud and abuse experts have extensive experience working with the AKS and helping life sciences manufacturers, distributors, and suppliers and healthcare organizations implement policies and practices in compliance with the AKS, including availing themselves of the law's safe harbors and working with HHS to develop new safe harbors. We have the practical perspective to help our life sciences clients understand how the proposed new and modified safe harbors will impact their activities and

operations. We can also offer creative and workable solutions to update existing control documents as necessary to comply with the new expectations while minimizing disruption to the business and ongoing operations.

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[1] The Proposed Rule states that a VBE would be at "substantial downside financial risk" under any of the following arrangements: (i) Shared savings with a repayment obligation to the payor of at least 40 percent of any shared losses; (ii) A repayment obligation to the payor under an episodic or bundled payment arrangement of at least 20 percent of any total loss; (iii) A prospectively paid population-based payment for a defined subset of the total cost of care of a target patient population; or (iv) A partial capitated payment from the payor for a set of items and services for the target patient population where such capitated payment reflects a discount equal to at least 60 percent of the total expected fee-for-service payments.