COMMENTS

of

WASHINGTON LEGAL FOUNDATION

to the

DEPARTMENT OF HEALTH & HUMAN SERVICES
Office of Inspector General

Concerning

MEDICARE AND STATE HEALTHCARE PROGRAMS: FRAUD AND ABUSE; REVISIONS TO SAFE HARBORS UNDER THE ANTIKICKBACK STATUTE, AND CIVIL MONETARY PENALTY RULES REGARDING BENEFICIARY INDUCEMENTS (Docket RIN 0936-AA10)

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Department of Health and Human Services
Cohen Building
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Re: Comments Concerning Creation of Safe Harbors to Anti-kickback Statute for Certain Value-Based Enterprises and Activities (RIN 0936-AA10)

Dear Sir/Madam:

Washington Legal Foundation ("WLF") appreciates the opportunity to submit these comments in response to the public notice published at 84 Fed. Reg. 55694 (Oct. 17, 2019). After detailing the interests of WLF in this proposed regulation, our comments will focus on the Office of Inspector General's ("OIG") decision to exclude certain entities from the definition of "value-based enterprise participants" based solely on their business status. OIG's poorly supported exclusion of those entities undermines the proposal's goal of advancing the transition of America's healthcare system to one that rewards value and will deprive federal healthcare programs and their customers of the benefits that value-based arrangements are generating in the private healthcare market.

I. Interests of WLF

Founded in 1977, Washington Legal Foundation is a public-interest law firm and policy center with supporters throughout the United States. WLF devotes its charitable resources to defending and promoting free enterprise, individual rights, a limited and accountable government, and the rule of law. The federal government's role in nearly

every facet of America's healthcare system, and the regulatory and enforcement authority that sweeping involvement grants to administrative agencies, implicate all of those principles. WLF *amicus* briefs, regulatory comments, and publications consistently advocate for clear legal standards, carefully targeted application of punitive federal statutes such as the False Claims Act and the anti-kickback statute, and agency respect for individual and business civil liberties.

WLF has filed comments with OIG on its authority to exclude individuals and businesses from participation in federal healthcare programs, and has appeared in federal court to oppose the Inspector General's unwarranted use of that power. *See*, *e.g.*, WLF Comments, *In re: HHS Revision of Exclusion Criteria*, Sept. 10, 2014; *Friedman v. Sebelius*, 755 F. Supp. 2d 98 (D.D.C. 2010), *aff'd*, 668 F.3d 813 (D.C. Cir. 2012). Alleged violations of the anti-kickback statute often trigger private lawsuits under the False Claims Act, a law whose judicial interpretation WLF has shaped through our *amicus* briefs. *See, e.g.*, *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989 (2016); *U.S. ex rel. Harman v. Trinity Industries, Inc*., 872 F.3d 645 (5th Cir. 2017).

Finally, in 2019, WLF published several legal-policy papers critiquing well-intentioned but constitutionally flawed policies intended to reduce pharmaceutical product prices, and participated in the appeal of a challenge to a drug-price disclosure speech mandate. *See, e.g.*, Howard L. Dorfman, *CMS's "International Pricing Index" for Medicare-Covered Drug Payment Ill-Conceived and Illegal*, WLF LEGAL OPINION LETTER, Dec. 13, 2019; Brief of Washington Legal Foundation, *Merck & Co. v. HHS*, No. 19-5222 (D. C. Cir.), filed Nov. 19, 2019.

II. OIG's Laudable Intentions and General Approach

OIG's intentions behind and general execution of its safe-harbors proposal are laudable. WLF supports this proposal's goal, and that of the broader HHS Regulatory Sprint to Coordinated Care of which OIG's proposed rule is a part, of "remov[ing] potential regulatory barriers to care coordination and value-based care." 84 Fed. Reg. at 55695. Pricing, contracting, and other arrangements based on tangible results, rather than on the volume of services or products offered, can more closely align health outcomes with costs. That could mean savings and improved care across all facets of healthcare delivery.

The nature of value-based arrangements, however, creates dire legal risks for participants in Medicare, Medicaid, and other federal healthcare programs. Absent clear safe harbors, regulators could conclude that compensation based on achieved outcomes, the availability of rebates and other risk-sharing devices, or the payment for services such as data collection that support a value-based contract are unlawful inducements. Violators of the anti-kickback statute ("AKS"), 42 U.S.C. § 1320a-7(b), face fines of up to $100,000 and 10 years in prison. The government can also levy separate fines for AKS infractions under the Civil Monetary Penalty law, and prosecutors and private *qui tam* relators can seek up to $21,000 for each "false claim" and treble damages under the False Claims Act. Stakeholders told OIG's in response to its 2018 Request for Information on value-based arrangements that those legal exposures strongly deter the pursuit of such arrangements in a government healthcare-program setting. *See* 84 Fed. Reg. at 55695. To its great credit, OIG listened: "There is compelling concern that uncertainty and

regulatory barriers—real or perceived—could prevent the best and most efficacious innovations from emerging and being tested in the marketplace." *Id*. at 55699.

III. OIG Should Not Exclude Healthcare-System Participants Based Solely on Their Business Status

Before detailing new safe harbors and laying out amendments to existing protections, OIG defines relevant terminology in the proposal's preamble. WLF will focus its comments on the definition of "value-based enterprise participant" ("VBE participant").

OIG defines VBE participant as "an individual or entity that engages in at least one value-based activity as part of a value-based enterprise." *Id*. at 55703. The key phrase is "engages in." An individual or entity is engaged if it is 1) "performing an action to achieve certain quality or outcome metrics and the providing or receiving of payment for such achievement" or 2) "coordinating care to achieve better outcomes or efficiencies." *Id*. OIG then provides examples of what types of entities could be VBE participants.

The proposal next devotes a lengthy subsection to entities that *cannot* be VBE participants, and thus whose value-based activity will *not* fall within the parameters of certain safe harbors. Pharmaceutical manufacturers, distributors or suppliers of durable medical equipment, prosthetics, orthotics, or supplies ("DMEPOS"), and laboratories are expressly excluded. Because those entities otherwise could "engage[] in one value-based activity," OIG offers two justifications for excluding entire industries and their companies. First, based on its "historical enforcement and oversight experience," OIG is "concerned that *some* companies . . . *might* misuse the safe harbors." *Id*. (emphasis added). Second, OIG believes that the excluded entities are "less likely to be on the front

line of care coordination and treatment decisions in the same way as other types of proposed VBE entities." *Id*. at 55704-05.

OIG's generalized statement that "some" pharmaceutical, DMEPOS, or laboratory companies "might" abuse the safe harbors' protection is an extremely thin reed on which to base the exclusion of every entity that occupies those particular industries. OIG does not explain why the safeguards it proposes for the new safe harbors are incapable of protecting patients and federal healthcare programs from possible abuses. Instead, it proposes the most sweeping possible safeguard: hundreds of businesses that provide products and services without which the American healthcare system cannot function are deprived of certain safe harbors if they engage in value-based activity.

Also, as OIG should be aware, several state Medicaid programs apparently don't share the federal agency's opinion that pharmaceutical companies' involvement in value-based enterprises increases fraud-and-abuse risks. Since 2018, for example, Oklahoma's Medicaid program has entered into value-based agreements with drug makers under which the companies pay rebates if their products don't perform as indicated. Jennifer Reck, *Oklahoma Signs the Nation's First State Value-Based Contracts for Rx Drugs*, Nat'l Academy for State Health Policy, Sept. 25, 2018, https://nashp.org/oklahoma-signs-first-medicaid-value-based-contracts-for-rx-drugs/. Michigan and Colorado have received approval from OIG's fellow HHS agency, the Center for Medicare and Medicaid Services, to enter into outcome-based contracts with drug makers. Alexander Dworkowitz, *et al.*, *Extending VBP Models into Medicaid Drug Purchasing: Challenges and Opportunities*, Health Affairs, May 22, 2019, https://www.healthaffairs.org/do/10.1377/hblog20190520.247063/full/.

OIG's second justification for industry-wide exclusions is equally suspect. In the second subsection under "VBE Participant," the proposal directly contradicts OIG's conclusion that the excluded entities are unlikely to be directly involved in coordination and treatment:

> [W]e are aware of companies that provide diabetes management services, leveraging devices that can be worn or attached to the body to monitor blood sugar levels and transmit that data, through an application to a cloud storage service, for review by patients and the clinicians managing the patients' diabetes care.

84 Fed. Reg. 55707. The wearable diabetes monitor that OIG references is generally categorized as a durable medical device. Therefore, if the business that provides the diabetes-care management service also makes the device itself (as has become common), that business, which is "on the front line of care coordination and treatment decisions," can't rely upon an AKS safe harbour if it participates in a value-based activity related to a federal healthcare program.

Companies in the pharmaceutical and DMEPOS industries are deeply involved in patients' treatment, and will become more so—to Medicare and Medicaid recipients' great benefit—if AKS safe harbors empower those business to participate in value-based activity. Producers of durable medical equipment, prosthetics, and orthotics are experts on how their inventions will perform in patients, and their continued involvement in patient care can often be critical to a device's success. DMEPOS representatives are also best situated to offer training, education, and care-coordination services.

Value-based arrangements between pharmaceutical manufacturers and private providers and payers are proliferating. Under those arrangements, financial risk-sharing

allows patients with challenging conditions to cost-effectively try different therapies. Such experimentation will reduce overutilization and increase patients' adherence to their doctors' drug prescriptions. Further, in the course of monitoring value-based drug arrangements, pharmaceutical manufacturers collect and analyze a great deal of patient data. That data not only improves the coordination of a patient's ongoing care, but also informs companies' improvement of their products or development of new ones.

Government healthcare programs and patients will not enjoy these benefits to the degree that private health plans and patients enjoy them if OIG's final value-based safe-harbor rule excludes the entire DMEPOS and pharmaceutical industries. OIG should reconsider its exclusion of these essential healthcare-delivery entities.

IV. Non-DMEPOS Device Companies Should Remain "VBE Participants"

In the second subsection under the preamble's "VBE Participant" section, OIG discusses the care-coordination virtues of "health technology companies," and expressly states that such companies are "eligible to be VBE participants under the proposed definition." 84 Fed. Reg. at 55705. OIG reserves its greatest enthusiasm for health-tech companies that strictly offer services, such as monitoring predictive analytics, and patient portals. The agency grudgingly acknowledges that some health-tech companies are "companies that have historically manufactured medical devices" and that have also "developed digital technologies that are used in conjunction with medical devices." *Id*.

That acknowledgement leads into numerous paragraphs of OIG verbal handwringing over allowing non-DMEPOS device manufacturers to benefit from the proposal's new AKS safe harbors. OIG suggests that the same justifications it cited for

excluding DMEPOS, pharmaceuticals, and laboratories—risk of abuse and lack of coordinating-care involvement—could justify exclusion of *all* device makers.

OIG's case for possibly excluding all device makers is as weak, if not weaker, than its explanation for singling out DMEPOS for exclusion. OIG not only relies upon the same "historical law enforcement experience" that it did for DMEPOS exclusion, but it also notes that companies whose "devices [were] used for invasive procedures" entered into "large False Claims Act settlements" over kickback allegations. OIG doesn't offer any further details or context for this example, such as whether federal officials or a *qui tam* relator initiated the action. A settlement, where the government has not proven its allegations in court and the defendant does not admit to wrongdoing, is also rather insubstantial proof that all medical-device makers are prone to fraud and abuse.

OIG also asserts that "it is not clear that all device manufacturers" play a front-line role in patient-care coordination and management. *Id*. As we note above when discussing the DMEPOS exclusion, device makers are experts in how their products work in the clinical setting. Their representatives are often directly involved in the most critical moments of patient care, such as when individuals with pacemakers undergo MRI or other scans during which the device may be compromised or cause complications. *See* Max Heerman and Daniel Smulian, *Medical-Device Representatives in the O.R.: Patient-Care Benefits and Legal Ramifications*, WLF LEGAL BACKGROUNDER, Apr. 7, 2017, https://www.wlf.org/2017/04/21/publishing/medical-device-makers-representatives-in-the-o-r-patient-care-benefits-and-legal-ramifications/.

Finally, if increasing efficiency and the quality of patient care, and reducing costs through value-based arrangements, are among OIG's goals in creating new AKS safe

harbors, excluding all device makers, including those who integrate digital health technology into their products, will directly undermine those goals. Neither government healthcare-program patients nor the programs themselves benefit if a final safe-harbor rule forces service providers and product makers into separate silos.

OIG should retain non-DMEPOS medical-device manufacturers as VBE-participants in a final rule.

V. OIG Entity Exclusion Should Be Activity-Based, Not Entity-Based

OIG also requests public comment on whether, instead of excluding entities from safe-harbor coverage based on industry type, the final rule should apply narrower factors, such as "product type, company structure, heightened fraud risk, or other factors." 84 Fed. Reg. at 55706. WLF encourages OIG to promulgate a final rule that utilizes those and other alternative factors, including the nature of the VBE activity, to determine VBE participation.

The federal government should not label entire industries, and consequently each company within those industries, as uniquely prone to fraud and abuse. That type of sweeping statement by an agency that regulates those companies' conduct carries a great deal of corrosive weight, and will fuel the animosity some in America regrettably have toward industries that provide life-enhancing and life-saving products. While specific businesses may have knowingly violated the anti-kickback statute, their transgressions should not be imputed to their market competitors.

In the preamble, OIG acknowledges another reason why an entity-based approach to exclusion is inapt: "the increasing integration of healthcare company business lines and the movement of traditional healthcare companies into digital health technology." *Id*. The

proposal also notes, in the discussion of health technology companies, that Medicare doesn't specifically define "device manufacturer," and any effort to define it for purposes of safe-harbor application could disqualify entities that offer the type of care-coordination services OIG favors. *Id*. at 55705.

Healthcare-business integration presents additional problems the proposal fails to mention. If a medical-device manufacturer that would otherwise qualify as a "health technology company" has in its portfolio of products a line of durable medical devices, prosthetics, or orthotics, that company cannot claim protection under some of the proposed safe harbors. In addition, some qualifying medical-device makers also produce pharmaceuticals. Because entities that manufacture pharmaceuticals don't qualify as VBE participants, that company couldn't claim protection of a safe harbour if its medical device becomes part of a value-based activity.

Further, in each of the safe harbors OIG proposes for value-based activities, the agency specifies that the safe harbors will not protect any VBE participant that accepts funds or other support from "an individual or entity outside of the applicable VBE." 84 Fed. Reg. at 55710; *see also id*. at 557561, 55763. An entity that the OIG proposal qualifies as a VBE participant could theoretically purchase goods or services at fair-market value from excluded pharmaceutical manufacturers or DMEPOS businesses. But, as attorneys who specialize in anti-kickback-statute compliance explained in an analysis of the OIG proposal,

> The nature of these strict restrictions vis-à-vis who is in and who is out, when it comes to the definition of VBE participants, however, will likely create more confusion and perceived barriers than clarity, leaving qualifying VBE participants wondering from which, if any, non-VBE

> participants they can buy their digital health technologies. We anticipate that VBE participants will struggle to find grey areas within which they feel comfortable buying items and services from non-VBE participants, without worrying about the perception that they have accepted funding or support from those excluded individuals.

Nancy Bonifant Halstead, *et al.*, *OIG and CMS Propose Sweeping Changes to Fraud and Abuse Regulations*, Reed Smith Client Alert, Nov. 20, 2019, https://www.reedsmith.com/en/perspectives/2019/11/oig-and-cms-changes-to-fraud-and-abuse-regulations-part-three.

Rather than paint entire industries with the broad brush of exclusion, OIG should judge entities' qualification for safe-harbor protection in the broader context of the activities in which the VBE participants engage and the type of arrangement at issue. If OIG retains the entity-based exclusion approach it has detailed in the proposed rule, however, WLF recommends that OIG refrain from excluding entities simply because those entities have affiliate relationships with DMEPOS, pharmaceutical, or laboratory businesses, or have product lines that include those entities' products.

Respectfully submitted,

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