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LEGAL ALERT

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OIG Issues Favorable Advisory Opinion on Research Incentives

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On December 20, 2016, the United States Department of Health and Human Services, Office of Inspector General ("OIG") issued Advisory Opinion No. 16-13, which permitted a clinical research site ("Research Site") to waive cost-sharing obligations and pay stipends to clinical study participants as incentives to participate in clinical research. In order to encourage participation in, and ensure compliance with, a study funded by the National Cancer Institute ("NCI") involving HIV-infected patients ("Study"), the Research Site sought to (i) pay Study subjects a stipend for the time and effort required to participate in the Study ("Current Arrangement") and (ii) waive out-of-pocket cost-sharing obligations (e.g., copayments, coinsurance and deductibles) incurred by Study subjects participating in the Study ("Proposed Arrangement"). While recognizing that the arrangements could potentially generate prohibited remuneration under the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b ("Anti-Kickback Statute") and/or constitute beneficiary inducements prohibited under the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a ("Civil Monetary Penalties Law"), the OIG determined that both the Current Arrangement and the Proposed Arrangement presented a minimal risk of fraud and abuse under these statutes and advised that it would not impose sanctions pursuant to 42 U.S.C. §§ 1320a-7a(a)(5) or (a)(7) or the exclusion authority at 42 U.S.C. § 1320a-7(b)(7).

The Anti-Kickback Statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a federal health care program. In addition, the Civil Monetary Penalties Law provides for the imposition of civil monetary penalties against any person who offers or transfers remuneration to a Medicare or state health care program (including Medicaid) beneficiary likely to influence the beneficiary's selection or receipt of reimbursable items or services from a particular provider, practitioner, or supplier of any such item or service. Although the definition of "remuneration" in the Civil Monetary Penalties Law contains limited exceptions for waivers of cost sharing obligations and the OIG has interpreted incentives that are nominal in value to not be prohibited by the statute, the OIG could not rely on such exceptions or interpretations to support either the Current Arrangement or the Proposed Arrangement.

In its analysis, the OIG found that the following unique aspects of the waiver and stipend arrangements mitigated the risk of fraud and abuse: (1) both arrangements were consistent with the policy objectives of the NCI and subject to government oversight; (2) the arrangements were reasonable means to address the difficulties of ensuring participation and compliance with the Study protocol; and (3) the Study was not designed or intended to serve commercial interests.

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Distinguishing the Study from industry-sponsored research, the OIG found it significant that the Study was entirely government funded by a grant from the NCI to the AIDS Malignancy Consortium and was developed without the input or support of any commercial enterprise. Furthermore, the NCI had already approved the grant of funds in connection with both the Current Arrangement and the Proposed Arrangement and selected a Study monitor with no financial interest in the outcome of the Study to monitor protocol compliance and frequently report data to the NCI thereby ensuring government oversight.

Also when considering the Current Arrangement and the Proposed Arrangement, the OIG recognized difficulties inherent to the Study protocol and the hurdles faced by the Research Site in ensuring the enrollment and protocol compliance necessary for a successful Study. The OIG acknowledged as valid the following concerns raised by the Research Site: (a) Study subjects may find the protocol-required services to be uncomfortable and time consuming; (b) Study subjects, which drew from under-represented minorities and varying socioeconomic backgrounds, might refrain from participation because of their inability to afford the burdensome cost-sharing obligations; and (c) Study subjects may not feel the urgent need to strictly comply with the protocol because the Study was designed to prevent rather than treat cancer. Without addressing these issues inherent to the Study protocol, the OIG understood that the Research Site would have difficulty ensuring the necessary Study subject compliance with the protocol-required schedule of visits and services for the Study to succeed.

Finally, the OIG considered the unique nature of the Study important to its analysis. The Study was a strategy study, not a treatment study for any specific treatment modality that may involve, benefit or advance the interests of commercial products or entities. The OIG found that the unique services required for the Study made it less likely that the Current Arrangement or the Proposed Arrangement would induce Study subjects to self-refer for unnecessary services.

The unique aspects of the Study as well as the Research Site's reasonable justifications supporting the Current Arrangement and the Proposed Arrangement allowed the OIG to issue a favorable yet narrow advisory opinion. Although both arrangements could potentially generate prohibited remuneration, the OIG concluded that these measures, designed to facilitate Study subject enrollment and ensure a successful Study, presented a minimal risk of fraud and abuse under the Anti-Kickback Statute and the Civil Monetary Penalties Law. While helpful under these specific circumstances, the OIG's rationale in Advisory Opinion No. 16-13 will not likely be applied broadly to encourage the use of similar clinical research incentives by industry sponsors.

For more information on the OIG Advisory Opinion No. 16-13 or other health care legal issues, please feel free to contact any member of the firm's Health Care Law Practice Group for further discussion.

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