OIG REJECTS A NEW TWIST ON POD LABS: EXCLUDING FEDERAL PROGRAM BUSINESS WON’T SAVE A TURNKEY PHYSICIAN LAB SCHEME

The OIG has rejected yet another pathology lab structure intended to avoid running afoul of the Anti-Kickback Act. Remember the now-extinct “pod labs,” where physician groups sent their specimens to a central processing location? Each practice had its own leased cubicle and equipment, and leased lab technicians rotated in and out of the pods? The idea was to create a centralized building that would satisfy the location and exclusive use requirements for the Stark group practice in-office ancillary services exception and avoid problems with Anti-Kickback Regulations. That model attracted the unfavorable scrutiny of the OIG. And now, the OIG has taken a hard look at another scheme and found it wanting.

In OIG Advisory Opinion 13-3, an independent clinical lab company (“LabCo”) put forth a similar scheme, but with a twist. LabCo would create a middleman management company (“Manager”) to contract with physician groups (“Groups”) wanting to set up turnkey clinical laboratories to handle their patient specimens. Each Group would have its own, full-time leased lab suite in a building owned by the Manager (“Suite”). The Manager would supply certain “shared” support services such as a common shipment receiving area, a business center (fax, printer, and copier), waste collection and cleaning services. The Manager would provide a variety of management services, including leased personnel and equipment for the Group’s lab operations and licensed use of its proprietary lab processes. A management contract would specify the services to be provided and all fees would be set in advance at fair market value.

Significantly, the model tried to avoid Anti-Kickback issues by requiring that the Groups not process specimens from any federal beneficiaries. Those paid for by federal programs would have to be sent to an outside reference lab chosen by the Group, which could include LabCo or its competitors. The reference lab would then bill the federal programs for the testing.

Rejecting the proposed arrangement, the OIG repeated its often-stated position that “carving out” federal program business will not insulate a proposal from Anti-Kickback analysis. Harking back to its Special Advisory Bulletin of 2003 on suspect contractual joint ventures, the OIG found that the turnkey arrangement proposed by LabCo would put Groups into the office-based lab business with little risk or capital investment. LabCo, which would otherwise have been a competitor for all of the Groups’ testing, was offering a scheme to carve up the
pie—the Groups take the commercial and self pay business, and LabCo will take the Medicare/Medicaid and Tricare work.

Excluding the federal business from the Group’s lab testing business does not eliminate Anti-kickback concerns. The OIG said that the profits generated by the Group through the private pay business would likely motivate physicians to over-order lab tests generally. The relationship with the Manager would cause the Groups to steer federally-paid tests (and specialized reference lab work such as confirmation and esoteric testing for ALL beneficiaries) to LabCo. Thus, despite the fact that individual pieces of the arrangement might fall with a safe harbor, the OIG felt the overall scheme would violate the Anti-Kickback prohibitions.

The take-away message for all arrangements that might implicate the Anti-kickback Statute: **cutting out the federal business doesn’t necessarily solve the problem.**

If you have questions about the issues addressed here, or any other matters involving Health Care Law, please contact your health care attorney or feel free to contact Kennedy Hudner at 860.240.6029/khudner@murthalaw.com, Stephanie Sprague Sobkowiak at 203.772.7782/ssobkowiak@murthalaw.com, or Paul E. Knag at 203.653.5407/pknag@murthalaw.com.