

Recent DOJ Settlements Involving DME Manufacturers Highlight Important Anti-Kickback Considerations

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The Department of Justice (“DOJ”) recently announced two settlement agreements, both involving durable medical equipment (“DME”) companies, following allegations that the companies had violated the Anti-Kickback Statute (“AKS”). The AKS, found at 42 U.S.C. § 1320a-7b, prohibits the exchange of anything of value (i.e., remuneration) with any intent to induce referrals for services or products reimbursable by federal health care programs. These settlements highlight two important reminders when it comes to complying with the AKS: (1) illegal remuneration can come in many forms and need not be monetary; and (2) commission-based compensation, while allowed for employees, is improper remuneration with regard to independent contractors.

The first settlement involved a DME manufacturer that allegedly misled federal health care programs, including Medicare, Medicaid, and TRICARE, by paying kickbacks to DME suppliers. Specifically, the manufacturers provided DME suppliers with data about physician

prescribing practices to aid their marketing efforts. In exchange, those suppliers then marketed the manufacturer’s products to providers. This resulted in DME suppliers submitting false claims for respiratory-related equipment following Respiroics’ illegal inducements. Under the settlement terms, Respiroics agreed to pay over \$24 million in total to the United States and various affected states. Respiroics also entered into a five-year corporate integrity agreement (“CIA”) with the U.S. Department of Health & Human Services Office of Inspector General (“HHS-OIG”).

This settlement agreement makes clear that *anything* of value – even data – can be considered illegal remuneration under the AKS. Even if there is no marginal cost involved from the perspective of the data provider, data nonetheless can have value to



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the recipient. Consequently, product manufacturers, health care providers and others should recognize that value in any form can be the basis for anti-kickback allegations.

The second settlement involved a DME manufacturer that produces knee braces and related products. It was alleged that the supplier paid an independent sales representative and the representative's company commission payments ranging from 20-35% of VQ's net revenue on every knee brace ordered by a particular set of providers. The providers then submitted claims for the braces allegedly contaminated by these kickbacks. The sales representative was able to "establish itself as the exclusive brace supplier" for several providers and collect millions of dollars in annual brace sales, according to the DOJ press release. Notably, this settlement was the result of an independently-prompted government investigation of Medicare claims data. Under the settlement terms, the DME manufacturer agreed to pay \$2.25 million and entered into a five-year CIA with HHS-OIG.



The issue of commission payments was also addressed early last year in *United States v. Mallory*, 988 F.3d 730 (4th Cir. 2021), wherein a federal court ordered a blood testing laboratory and its contracted sales agents to pay more than \$100 million in damages after finding that the lab's commission-based compensation to its contractors violated the AKS. These recent events illustrate that commission-based compensation arrangements with independent contractors are still an issue whenever federal health care programs are involved. And while there is an AKS safe harbor for commission payments to

employees (42 C.F.R. § 1001.952(i)), the Department of Health and Human Services has made clear that commission payments for contracted services are not likewise protected. The DOJ has established its intent to aggressively scrutinize and prosecute such arrangements.

In summary, these DME manufacturer settlements underscore two important AKS guidelines for all health care service and equipment providers: (1) be aware of untraditional items of value, such as data, that could be considered illegal remuneration; and (2) avoid commission-based compensation arrangements with independent contractors whenever federal program provide reimbursement for the products or services.