



Know Your Rights...

Device companies employ numerous tactics intended to protect their bottom line from competition. Oftentimes these tactics – some of which may be illegal – are aimed at clinicians and hospitals and are intended to stop or hinder your reprocessing program. Below we address two of the common challenges facing hospitals and provide you with information on how to exercise your rights when making purchasing decisions.

Kickbacks

Device companies compensate physicians in numerous ways – from paying consulting fees to awarding research grants.

Although it is permissible for device companies to compensate physicians for their help in developing and validating new technologies, it is illegal for a device company to compensate a physician in exchange for the physician's influence in hospital purchasing decisions (*e.g.*, anti-reprocessing policies).

Under the *Federal Healthcare Anti-Kickback Act*, it is a criminal offense to solicit or receive any remuneration intended to induce the purchase, order, or recommendations of the purchase or order of items reimbursable by a federal healthcare program.¹

Both sides of an impermissible kickback transaction – the company and the physician – are subject to serious penalties, including exclusion from CMS reimbursement.

Exercise Your Rights

Hospitals can detect impermissible kickback arrangements and prevent physicians with ties to device companies from influencing purchasing decisions by taking these steps:

1. Require physicians to periodically disclose any relationships with device companies; and
2. Develop a policy whereby physicians with ties to companies are prohibited from participating in purchasing decisions.

Contracts

Device companies view reprocessing of single-use devices (SUDs) as a growing threat to their profit margins. To combat this threat, they have adopted potentially illegal, anticompetitive practices aimed at limiting hospitals' ability to reprocess.

Under the *Sherman Act*, exclusive dealing arrangements can be an improper means of maintaining a monopoly.² Device companies often include these types of potentially illegal provisions in their sales contracts. For example:

- A company will sell its SUDs to the hospital, *provided that* the hospital agrees not to reprocess those SUDs.³
- A company will sell its SUDs to the hospital at a discounted rate, *provided that* the hospital agrees not to reprocess those SUDs.⁴
- A company threatens not to supply the hospital with its full line of products, *unless* the hospital agrees not to reprocess.⁵

Exercise Your Rights

Hospitals can take control of the terms of their sales contracts and prevent device companies from dictating whether they will reprocess by taking these steps:

1. Establish a policy that permits reprocessing and provide that policy to all vendors;
2. Simply cross out language in contracts that limits the hospital's ability to reprocess;
3. If a company continues to pressure you, contact your legal or risk management department for assistance.
4. If you still feel pressured or uncomfortable -- don't sign.

References

¹ See 42 U.S.C. § 1320a-7b(b).

² *United States v. Grinnel Corp.*, 384 U.S. 563 (1966).

³ See generally *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181 (3d Cir. 2005); *LePage's, Inc. v. 3M*, 324 F.3d 141 (3d Cir. 2003); *United States v. Microsoft*, 253 F.3d 34 (D.C. Cir. 2001).

⁴ *Id.*

⁵ See *Dentsply Int'l*, 399 F.3d at 190; *LePage's*, 324 F.3d at 162.