

Considerations for Contracting and Provision of Placed Equipment

Background

This document is to bring to the attention of members the legal and compliance risks that could arise from the placement of equipment for no, or little money, in exchange for contractual assurances that hospitals will pay for the equipment, or finance it, through the purchase of other products and consumables. Examples of arrangements for accessing equipment are provided in Annex 1; not all these examples are in the scope of this document, as this document is not intended to cover consignment arrangements, whereby the title remain with the supplier until the product is used, at which point it is invoiced or rental/leasing arrangements at market rates, and on arm's length terms. The scope of the document is for UK based operating companies, and is intended to highlight good practice considerations.

Placement arrangements for equipment with minimal, or no additional charge, are becoming common practice in the NHS, including NHS Supply Chain issuing tenders asking for bids that include such arrangements. There have been legal cases that have brought to the fore the risks associated with placement equipment contracting and the HealthTech sector organisations engaging in such arrangements should take note of these cases, and the considerations in this document, to ensure that suppliers are not at risk of falling foul of applicable laws. Anti-corruption/anti-bribery and competition laws all carry potential consequences, including possible reputational damage.

Current Situation

It is recognised that, as common practice, a large number of suppliers will have equipment placed with NHS customers 'free of charge', or at a nominal charge, with contracts in place for consumables ostensibly to cover the cost (i.e. purchase price or rental free equipment) of that equipment. While both parties may believe it is clear and transparent, placement of equipment gives rise to accounting, contractual and financial complexity, which could give rise to legal risk that organisations in the HealthTech sector should consider when entering into such agreements.

In one case, the U.S Government alleged that the company lacked adequate controls to ensure the appropriate accounting treatment for the arrangements, or to record the transactions appropriately in its books and records. In doing so (or not doing so) the company also failed to address the risks associated with its placement of medical equipment at hospitals or clinics for no or little money down in exchange for contractual assurances. By way of reminder, the Foreign Corrupt Practices Act (FCPA) may not apply to every company operating in the UK healthcare sector, but do not be quick to assume that your company is outside its scope. The FCPA is very wide-ranging in its application and applies to foreign subsidiaries of a US entity which does business in the US. UK companies, and foreign companies carrying on all or part of a business in the UK, should also be aware of the effect of the UK Bribery Act 2010 (UKBA) and its implications. Although the UKBA does not contain similar 'books and records' provisions, a company's only defence to the corporate bribery offence is to demonstrate that it had adequate procedures in place to prevent bribery taking place.

While in the UK much of the contracting is with the NHS, and therefore governed by public procurement regulations, that may ensure risks are mitigated, suppliers do contract with private providers and suppliers are advised to consider this document for private sector contracts as well.





Considerations

When entering into an arrangement to provide any equipment or infrastructure that is not paid for directly at the outset, i.e. it is considered 'placed' and is associated with future sales, members should consider taking the following steps:

> **Audit**

If the location of placed equipment is not already known, suppliers could undertake an audit of, or make enquiries to confirm, the location of placed equipment, and to assess placement agreements against the following criteria; criteria may be as per headings below, but other criteria may be necessary.

> **Company Policy**

Companies can consider their existing practices and whether it is appropriate to put in place a policy setting out the requirements for entering into an agreement with customers to place any equipment as part of a contract.

> **Clear and Transparent Contractual and Financial Terms**

Members can consider whether the documentation which they have in place is appropriate and reflects the terms negotiated with the hospital/clinic, including (crucially) payment terms, the duration of the placement, the amount or value of the relevant consumables, with appropriate detail, which should be bought by the customer, and how any differences between purchase requirements and actual sales will be managed. Terms and conditions/appropriate contract documentation should be in place for the duration of the equipment placement period. Members should consider whether it is appropriate to include anti-bribery and corruption wording within such documents, and/or to incorporate the terms of an appropriate anti-bribery policy and/or Code of Conduct by reference. Approval and signature (where applicable) of the relevant documentation should be undertaken at an appropriate level within the organisation.

> **Governance and Oversight of the Contract**

Members can consider the governance they have in place relating to the oversight of the agreement or contract, which should be clear and rolled-out appropriately. Appropriate management through the life of the agreement or contract is important to ensure "compliance rates" with respect to the contractual purchase and other binding obligations. Underperforming agreements, or agreements in respect of which discrepancies or issues have been identified, should be addressed as necessary and in a timely manner as much as is possible within the gift of the supplier. Approvals and sign off should be undertaken at an appropriate level within the organisation.

> **Resources Required**

Consideration should be given to the resources required from both the supplier and the customer to meet their respective agreement obligations, including any and all training and support for the equipment, and the management of the agreement itself.



Annex 1:

Examples of Types of Equipment Arrangements

Equipment supplied subject to various leasing, deferred purchase or rental arrangements

There is a wide range of different leasing or asset purchase structures available as financing techniques for buying assets such as capital equipment, some of which can also be employed by member companies and their healthcare organisation (HCO) customers.

Broadly defined, leasing, where a HCO makes regular payments (which may be calculated in a variety of ways) and has an option at the end of the term to buy the equipment, is one way to finance the use or the purchase of equipment. The alternative would be to pay the purchase price upfront, or else having to borrow the purchase price and then use the equipment to provide security for the loan. For avoidance of doubt, in a leasing setup, the [property] title remains with the company, unless the option is exercised at the end of the term.

Leasing agreements are varied and can include finance leases, operating leases, hire purchase arrangements and also sale and leaseback structures. Other asset purchase arrangements have similarities with leasing arrangements but are sale agreements in substance, such as conditional sale agreements and credit sale agreements. The instalment payments in these type of sale arrangements may be calculated in different ways (e.g. fixed amounts; determined by the level of usage of the equipment). Title to the equipment may pass at inception or only after all payments have been made and any other specific conditions have been met, for example that the user has repaired and maintained the equipment.

Rental agreements operate similarly to a leasing arrangement, in the sense that payments are made to enable HCOs to have the use of the equipment over a defined term, but without having an option to purchase the equipment at the end of the term, e.g. 'pay per test' arrangements for laboratory equipment.

'Package deals'

Equipment may be supplied as part of 'package deals' with HCOs. Such deals are commercial arrangements whereby the purchase of a particular piece of equipment is linked to the provision of certain associated benefits as part of the purchase price, such as associated consumables, apparatus and/or software for using with the equipment, the provision of training on its use and/or the services to deliver the equipment, e.g. via a homecare delivery service.