AdvaMed Best Practices Guidance on Sample Products, Loaned Products, and Consignment Products

Definitions:

Evaluation Products:

Single-Use (also called “sample products”): Section XII of the AdvaMed Code of Ethics addresses single-use evaluation products. These are products provided to Health Care Professionals (HCPs) at no charge to allow HCPs to assess the appropriate use and functionality of the product and determine whether and when to use, order, purchase, or recommend the product in the future. Single-use evaluation (sample) products do not include other types of no-charge products, such as those provided as a charitable donation, or those provided as part of a discount arrangement.

Multiple-Use (also called “loaned products”): Section XII of the AdvaMed Code of Ethics also addresses multiple-use evaluation products. These products may be provided to HCPs at no charge to allow HCPs to assess the appropriate use and functionality of the product and determine whether and when to use, order, purchase, or recommend the product in the future. Multiple-use evaluation (loaned) products, as discussed in this document, do not include products loaned as part of a warranty agreement.

Note: This guidance document is not intended to address demonstration products (i.e., unsterilized products or mock-ups of such products used for HCP and patient awareness, education, and training) or product samples provided to HCPs that are intended for direct distribution to patients (e.g., patient benefit items such as starter kits).

Consigned Products: Consigned products are Medical Technologies that are provided to a Health Care Professional for use in a patient care setting; although Consigned products are located at the HCP institution, the Company retains ownership of the product until such time as it is used. At that time, the product is considered to be sold to the HCP.

Factors to Consider:

A Company should consider whether federal or state law, for example, Physician Payment Sunshine, may require reporting the value of certain products provided to HCPs. A Company should also

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1 Under the federal Physician Payment Sunshine law, the provision of certain loaned evaluation products or samples to an HCP may constitute a reportable “transfer of value” to a “covered recipient.” For example, an evaluation product that is loaned for longer than 90 days constitutes such a transfer, and must be valued and reported.
consider the whether provision of certain products may be subject to taxation under the Medical Device Excise Tax.²

**Evaluation Products:**

- Appropriate reasons for providing single-use or multiple-use evaluation products to an HCP may include:
  - The HCP has not recently purchased or used the product (i.e., the HCP is not familiar with the product);
    
    Note: The AdvaMed Code defines HCP broadly; the term can include hospitals and other large institutions. In some situations, it may be appropriate to provide samples or loaned devices to an HCP that is currently purchasing the product. For example, a sample or loaned device might be provided to an individual physician in one hospital department, even though other physicians in other departments may be familiar with the product.
  - The product is being marketed for a new indication or a new surgical technique; or
  - The Company or the HCP have identified a need for training on the use of the device.

- For single-use evaluation products, the quantity provided should not exceed the amount reasonably necessary for the adequate evaluation of the products. For multiple-use evaluation products, the evaluation period should not exceed the length of time reasonably necessary for the adequate evaluation of the products.

  Note: Companies should consider adopting policies and procedures to implement this consideration.

  Note: FAQ #53 of the AdvaMed Code explains that the specific length of time necessary for an HCP to assess a loaned product will depend on the frequency of anticipated use, the duration of required training, the number of HCPs who will need to evaluate the product, the length of time necessary to evaluate different product features, and similar considerations. As described in FN1, the federal Physician Payment Sunshine law considers a non-reportable evaluation product to be one that is loaned for fewer than 90 days.

- The no-charge nature of the product should be clearly communicated in writing to the HCP.

  Note: The timing and the form of this written communication may vary according to the product type, the Company's billing arrangements with the HCP, and other considerations.

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² Under IRS excise tax rules, the provision of certain no-charge products may nevertheless constitute a “use” or “sale” of a taxable product.
Note: Federal or state health care programs may restrict HCPs’ ability to bill or seek reimbursement for sample or loaned products; HCPs are obligated to comply with these restrictions.

- Additional considerations for multiple-use evaluation products:
  - The Company and the HCP should enter into an agreement which clearly specifies (1) the length of the evaluation period and (2) the terms and conditions for loaned products that have not been returned within the evaluation period (e.g., an automatic rental term following the evaluation period).
  - The Company should establish procedures to track loaned devices and retrieve the loaned product at the end of the evaluation period.

Consigned Products:

- The Company should enter into an agreement clearly specifying the terms of the consignment arrangement.
- The Company should specify the number of products consigned.
- The Company should require that the HCP segregate consigned products from other types of products, such as products the HCP has already purchased or products under the control of the Company’s representatives (i.e., “trunk stock”).
- The Company should implement procedures to periodically take inventory of consigned devices in order to:
  - Bill the HCP for products used; and
  - Re-stock new products and remove obsolete or expired products if necessary.
- The Company should implement a process for reconciling any discrepancies between the Company’s records of the number of products consigned and the number of products used or verified during inventory.
- The Company should consider in advance how to allocate the risk of loss for lost or destroyed consigned products.
- The Company may also consider implementing systems to allow for real-time tracking of consigned devices (e.g., portable scanning technology).
- If a Company enters into an agreement to rent storage space from an HCP to store consigned products, any rental payments should be consistent with fair market value.