



AdvaMed supports appropriate disclosure of relationships between medical technology companies and physicians. Strong ethical standards are critical to ensuring appropriate collaboration between the medical device industry and physicians. Unlike other health care industries, medical device companies must rely on physician experience and feedback to develop better treatments for patients. Likewise, because the effectiveness of a device depends on a physician's skill in using it, it is essential that physicians receive education and training. Disclosure legislation should be limited to information that is helpful to patients in their decision-making process, should be available in a meaningful and easily-understood format that provides the appropriate context for patient education, must not be unnecessarily burdensome, should not compromise proprietary information, and should preserve arrangements with physicians beneficial to patients and continued medical innovation.

As Congress moves forward with disclosure legislation, we recommend the following:

Ensuring a Fair and Level Playing Field

- Federal legislation should expressly preempt State laws requiring disclosure of relationships with physicians. It would be overly burdensome and costly to require manufacturers to comply with 50 different State standards for tracking and reporting, and it would be more difficult for patients to access and use the disclosed information in a meaningful way. Additionally, this new Federal standard will be very broad and more comprehensive than existing standards.
- The policy goals of this legislation would be better achieved based on a reporting threshold reflecting a company's aggregate annual payments to physicians, rather than the annual revenues of the company. AdvaMed recommends that the \$100 million annual revenue threshold be deleted, and replaced with a standard triggering reporting obligations for companies that make \$250,000 in aggregate annual reportable payments to physicians.
- Physician-owned manufacturers, distributors, and group purchasing organizations should be required to comply with the requirements of disclosure legislation, regardless of whether they meet any threshold that may be included in the legislation to limit the types of manufacturers subject to disclosure requirements. Patients should be informed about the practices of companies in which physicians have both an equity ownership interest and who are also major revenue generators for the company.

Reporting Content That Is Tailored and Appropriate to the Medical Device Industry

- Rather than broadly requiring the reporting of "payments or other transfers of value" to physicians, the legislation should be more tailored and require reporting only of the specifically enumerated types of payments set forth in the legislation.
- Companies should not be required to report gifts of medical textbooks (regardless of media form), anatomical models, or items having a fair market value of less than \$100 that benefit patients, relate to the physicians' work, or serve a genuine educational function. This threshold is consistent with the AdvaMed Code of Ethics and other life sciences industry codes, and this will ensure that significant payments are disclosed while minimizing administrative challenges for medical technology companies involved in tracking such transactions.

- In order to protect proprietary information about a company’s products under development from competitors, consulting arrangements with physicians should be disclosed only after a product is approved or cleared by the FDA, unless the physician is already a user of other products manufactured or sold by that company. This “delayed reporting” is consistent with the recently enacted clinical trials database provisions of the FDA Amendments Act.
- All payments should be reported at the recipient level only, and companies should not be charged with a further obligation to identify all physicians tenured, employed by or owning a recipient entity, as those individuals often change over time. Tracking such relationships may, in fact, be impossible for a manufacturer given that physicians may enjoy privileges at several hospitals or even group practice entities and such information is not accessible to manufacturers.
- Disclosure requirements should not include reporting of discounts, rebates, or other pricing information. Such reporting would inhibit competition and could actually result in increased prices; in fact, experts find that revealing actual sales prices may result in increased costs as variation in prices and discounts converge. In addition, substantial sales of medical devices are to institutions, like hospitals, and not directly to physicians – and discounts and rebates to such customers are already addressed by current Anti-Kickback Statutes and implementing regulations.
- Reporting of product education and training provided to physicians should be limited to the value of travel, meals, and compensation, if any. Legislation should not require companies to impute a value to the actual education and training provided nor allocate that value among participating physicians.
- Legislation should exclude any technical support and economic or reimbursement information manufacturers provide to physicians, hospitals, and other customers from any reporting obligations. Technical support is typically included in the price of the products and has no separate or assigned value that can be attributed to individual physicians. Economic and reimbursement information provided to promote correct and accurate coding and billing is also typically included in the purchase price of manufacturer’s products. Such information is often publicly available on the manufacturers’ websites. There is no established process for establishing the value of such information and it would be impossible to track and allocate the value of such information.
- Similar to the exemptions for drug samples, the legislation should exempt from disclosure sampling in the device industry, including demonstration units and models for physician and patient evaluation.
- Companies anticipating or involved in litigation often utilize physicians to serve as expert witnesses or provide other expertise. Disclosure of such relationships could violate attorney-client privilege, unfairly require the disclosure of legal strategies and should therefore be exempt from the requirements of the legislation.

Providing Clear and Meaningful Information to Patients

- In order to ensure that patients receive useful information and do not mistakenly form the impression that all payments to physicians are suspect, legislation should require that publicly posted data include information on the context surrounding each payment, as designated through rulemaking. The choice to submit such contextual information should be left to company discretion. For example, companies should be able to specify that payments in the context of education and training are related to training physicians to use a medical technology safely and effectively.
- The legislation should authorize appropriations to ensure that the overseeing agency has the resources necessary to set up and implement a centralized database and disclosure program, designed to ensure that the information provided to the public is helpful and easily understandable to patients.

Maximizing Confidence in the System by Minimizing Errors

- The effective date for the legislation should be at least two years after the date of enactment, to allow the highly diversified medical technology industry sufficient time to develop or refine integrated reporting and tracking systems to comply with the new law.
- Consistent with the House legislation, disclosing entities should be required to report annually on June 30th, with reports including payment information from the preceding calendar year.
- The tracking requirements contained in the legislation should be made more reasonable by making clear that disclosure of payments may be made in a dollar range (e.g. reported in \$25,000 increments), rather than at a specific dollar amount where the potential for inadvertent and clerical error is significant.
- For all manufacturers subject to this legislation, there should be a manufacturer option to report at the holding company or divisional level.

Protections from Unintended Consequences

- The legislation should provide for an administrative appeals process that disclosing entities can utilize before a decision to impose penalties is made. Given the breadth and depth of systems and procedures that this legislation will require medical technology companies to undertake, the legislation should make clear that companies have an opportunity to correct inadvertent reporting errors. Penalties should be considered and imposed only when the disclosing entity knowingly fails to submit information that is required.
- The legislation anticipates the disclosure of a wide range of payments in each submission made by the disclosing entity, and any error can trigger penalties of up to \$100,000 per error. The potential exists for accounting errors to quickly add up to millions of dollars in penalties – which in our view is an excessive response. Therefore, the legislation should cap the total amount of penalties for each submission.
- The legislation should include a hold harmless provision to protect manufacturers who will be required by federal law to report against liability from doctors, or others who are not required to report.
- The legislation should expressly state that violations of this statute cannot form the basis of a government or private claim that the reporting company violated another statute or committed a tort.