

Seller Beware

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With an eye toward patient convenience and movement toward more of a “one-stop-shopping” experience, increasingly physicians are offering patients the option of purchasing health-related products in their offices. Before incorporating products into your practice, it is important to understand that there are legal and ethical issues that must be taken into consideration.

No rule exists prohibiting physicians from selling products in their offices — generally. However, there are prohibitions and regulations regarding the sale of specific products (and devices). For example, if a product is not FDA-approved, physicians should strongly consider refraining from advertising or selling the product in their offices, as there is a greater likelihood of potential exposure should a patient have an adverse reaction since the practice knew or should have known the product may not have passed muster or been properly tested. Another example of prohibitions on specific products, all designated health services are not authorized to be sold and reimbursement paid unless applicable laws are being complied with (eg, durable medical equipment is prohibited from being sold by practices under the Stark Law unless the practice meets certain requirements and an applicable Stark Law exception applies).

Even if the products being offered for sale are permissible (eg, vitamins, nasal washes, skin care products) there are regulations of which physicians need to be aware. For instance, New York Education Law 6530 considers it professional misconduct to exercise “undue influence on the patient, including the promotion of the sale of services, goods, appliances, or drugs in such manner as to exploit the patient for the financial gain of

the licensee or of a third party.” Therefore, physicians need to take action to alleviate any potential for undue influence. As an example, patients should be made aware of the availability of the product elsewhere.

Of note, the American Medical Association is not supportive of selling products and states so in Ethics Opinion 8.062 (www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion8062.page) which states:

“The sale of non-health-related goods by physicians presents a conflict of interest and threatens to erode the primary obligation of physicians to serve the interests of their patients before their own. Furthermore, this activity risks placing undue pressure on the patient and risks demeaning the practice of medicine.”

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The opinion goes on to state that with limited exception, physicians “*should not sell non-health-related goods from their offices or other treatment settings.*”

A related opinion 8.063 (www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion8063.page) addresses the sale of health-related products from physicians’ offices. The opinion specifically states that selling includes endorsing products patients purchase elsewhere that result in direct remuneration for the physician and:

“In-office sale of health-related products by physicians presents a financial conflict of interest, risks placing undue pressure on the patient, and threatens to erode patient trust and undermine the primary obligation of physicians to serve the interests of their patients before their own.”

Further, the opinion offers guidance for physicians who elect to sell products in their practices (or on their websites), as follows:

- (1) Physicians who choose to sell health-related products from their offices should not sell any health-related products whose claims of benefit lack scientific validity. When judging the efficacy of a product, physicians should rely on peer-reviewed literature and other unbiased scientific sources that review evidence in a sound, systematic, and reliable fashion.
- (2) Because of the risk of patient exploitation and the potential to demean the profession of medicine, physicians who choose to sell health-related products from their offices must take steps to minimize their financial conflicts of interest. The following guidelines apply:
 - (a) In general, physicians should limit sales to products that serve the immediate and pressing needs of their patients. For example, if traveling to the closest pharmacy would in some way jeopardize the welfare of the patient (eg, forcing a patient with a broken leg to travel to a local pharmacy for crutches), then it may be appropriate to provide the product from the physician's office. These conditions are explained in more detail in the Council's Opinion 8.06, "Prescribing and Dispensing Drugs and Devices," and are analogous to situations that constitute exceptions to the permissibility of self-referral.
 - (b) Physicians may distribute other health-related products to their patients free of charge or at cost, in order to make useful products readily available to their patients. When health-related products are offered free or at cost, it helps to ensure removal of the elements of personal gain and financial conflicts of interest that may interfere, or appear to interfere, with the physician's independent medical judgment.
 - (c) Physicians must disclose fully the nature of their financial arrangement with a manufacturer or supplier to sell health-related products. Dis-

closure includes informing patients of financial interests as well as about the availability of the product or other equivalent products elsewhere. Disclosure can be accomplished through face-to-face communication or by posting an easily understandable written notification in a prominent location that is accessible by all patients in the office. In addition, physicians should, upon request, provide patients with understandable literature that relies on scientific standards in addressing the risks, benefits, and limits of knowledge regarding the health-related product.

- (d) Physicians should not participate in exclusive distributorships of health-related products which are available only through physicians' offices. Physicians should encourage manufacturers to make products of established benefit more fairly and more widely accessible to patients than exclusive distribution mechanisms allow.

AMA Ethics Opinion 8.063.

If you are currently selling products or plan to in the future, I recommend you review the above referenced opinions (and opinions referenced within those opinions) in greater detail, and contact your healthcare attorney to review any intended activity to ensure compliance. With the increased level of scrutiny on all practices today, it is imperative to limit any potential exposure.

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