

## **Receiving compensation for moving patients from brand-name drugs to generics: ethical and legal issues<sup>1</sup>**

American Medical Association (AMA) Policy H-125.984 recognizes that generic drugs can be less costly alternatives to brand-name products. H-125.984 also states that physicians should be free to use either the generic or brand name in prescribing drugs for their patients, and physicians should supplement medical judgments with cost considerations in making this choice. Recently, the AMA has learned that some health insurers are offering to pay physicians to switch patients from brand-name drugs to generic. The AMA has received numerous inquiries from the Federation of Medicine concerning the legality or ethical propriety of accepting this type of compensation. This question-and-answer document attempts to address these legal and ethical considerations.

### **Will physicians violate any federal laws by accepting the health insurer's payment?**

A physician accepting payment from an insurer in exchange for moving a patient from a brand name to a generic drug could potentially face both criminal and civil liability exposure under the federal antikickback statute.<sup>2</sup> The antikickback statute prohibits individuals or entities that knowingly and willfully offer or receive anything of value (1) in order to induce or reward the referral of business, or (2) in return for ordering any good, if payment for the good or referred business is at least partially made by a federal health care program (e.g., Medicare Advantage). Accepting payment for moving a patient from a brand name to a generic could be viewed as an antikickback statute violation (e.g., the physician receiving something of value, such as a cash payment, to prescribe the generic instead of the brand-name drug). Violations of this law are punishable by up to five years in prison, criminal fines of up to \$25,000, civil monetary penalties up to \$50,000, and exclusion from participation in federal health care programs like Medicare.

The Michigan State Medical Society has asked a health insurer to change the way it promotes the compensation to physicians so it is clear that any payment is for the purpose of fairly compensating the physician for otherwise unpaid physician work relating to moving the patient from the brand name to the generic (e.g., time and effort taken “to track the patient to determine if the change is medically appropriate and counsel the patient about making the change”).

### **May a physician lawfully accept the payment if the payment only applies to patients who have commercial insurance or whose care is funded by a state governmental program?**

The answer to this question depends on the laws of the state in which the physician practices. At least 37 states have some type of antikickback statute, and some of these statutes apply in commercial insurance contexts. If the amount of payment offered to the

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<sup>1</sup> **NOTICE:** This document provides only general legal information and not legal advice. The reader should not rely on this information when dealing with personal legal matters. Instead, the reader should obtain advice from retained legal counsel.

<sup>2</sup> Section 1128B(b) of the Social Security Act (42 U.S.C. 1320a-7b(b)).

physician to move the patient from the brand-name drug to the generic exceeds the fair market value of the physician's time and effort, the physician could be exposed to liability under a state antikickback statute. See Appendix A for a list of citations to state antikickback statutes.

**What if a physician's acceptance of the compensation does not implicate any state or federal antikickback statutes? Are there any other potential liability concerns?**

AMA policy acknowledges the legitimacy of generic substitution. AMA policy also states that physicians should use their medical judgment when deciding to make a substitution. In some circumstances, a physician might have to respond to medical liability allegations if a switch resulted in patient injury. The ability to respond effectively to these allegations may be made more difficult if the physician received payment from a health insurer to make the switch.

**Are there any ethical concerns raised when a physician accepts payment for changing a patient from a brand-name drug to a generic?**

Accepting payment for changing patients from a brand-name drug to a generic may raise ethical concerns that are expressed in a number of ethical opinions that have been published by the AMA's Council on Ethical and Judicial Affairs (CEJA). For example, "E-8.03 Conflicts of Interest: Guidelines" states, "Under no circumstances may physicians place their own financial interests above the welfare of their patients." "E-8.06 Prescribing and Dispensing Drugs and Devices" adds, "Physicians should prescribe drugs, devices, and other treatments based solely upon medical considerations and patient need and reasonable expectations of the effectiveness of the drug, device or other treatment for the particular patient." Similarly, "E-8.13 Managed Care" states, "Efforts to contain health care costs should not place patient welfare at risk...Physicians should insist that any incentives to limit care must be disclosed fully to patients by plan administrators...." These and other ethical pronouncements from CEJA are attached to this document in Appendix B. A physician should consider these pronouncements as part of a decision to consider whether it is appropriate to accept payment in exchange for moving a patient from a brand-name medication to a generic.

## APPENDIX A<sup>3</sup>

*Alabama:* Ala. Code § 22-1-11.  
*Arizona:* Ariz. Rev. Stat. § 13-3713.  
*Arkansas:* Ark. Code Ann. § 20-77-902.  
*California:* Cal. Bus. & Prof. Code § 650; Cal. Welf. & Inst. Code § 14107.2; Cal. Health & Safety Code § 445.  
*Colorado:* Rev. Stat. Ann § 12-36-125.  
*Connecticut:* Conn. Gen. Stat § 53a-161c.  
*Delaware:* Del. Code Ann. tit. 31, §§ 1005, 1007.  
*District of Columbia:* D.C. Code Ann. § 4-802.  
*Florida:* Fla. Stat. §§ 395.0185, 456.054; Fla. Stat. § 409.920.  
*Illinois:* 305 Ill. Comp. Stat. 5/8A-3; 225 Ill. Comp. Stat. 60/22.  
*Indiana:* Ind. Code § 12-15-24-2.  
*Kansas:* Kan. Stat. Ann § 21-3847.  
*Kentucky:* Ky. Rev. Stat. Ann. § 216.2950.  
*Louisiana:* La. Rev. Stat. Ann. § 37.1745.  
*Massachusetts:* Mass. Gen. Laws Ch. 175H, § 3.  
*Michigan:* Mich. Comp. Laws § 752.1004.  
*Mississippi:* Miss. Code Ann. §§ 43-13-207 to 43-13-225.  
*Missouri:* Mo. Rev. Stat. § 191.905.  
*Montana:* Mont. Code Ann. §45-6-313.  
*Nevada:* Nev. Rev. Stat. § 616D.390.  
*New Hampshire:* N.H. Rev. Stat. Ann. § 167:61-a.  
*New Jersey:* N.J. Stat. Ann. §30:4D-17.  
*New Mexico:* N.M. Stat. Ann § 30-44-7.  
*New York:* N.Y. Soc. Serv. Law § 366-d.  
*North Carolina:* N.C. Gen. Stat. §§ 90-401, 90-402.  
*Ohio:* Ohio Rev. Code Ann. § 3999.22.  
*Oklahoma:* Okla. Stat. tit. 56, §§ 1005 to 1006.  
*Pennsylvania:* Pa. Stat. Ann. tit. 62, § 1407.  
*Rhode Island:* R.I. Gen. Laws § 5-48.1-3; R.I. Gen. Laws § 40-8.2-3.  
*South Carolina:* S.C. Code Ann. § 44-113-60.  
*South Dakota:* S.D. Codified Laws § 22-45-4.  
*Texas:* Tex. Occ. Code Ann. § 102.001.  
*Utah:* Utah Code Ann. §§ 26-20-4, 26-20-9.  
*Virginia:* Va. Code Ann. § 32.1.315.  
*Washington:* Wash. Rev. Code § 74.09.240.  
*West Virginia:* W. Va. Code § 9-7-5.  
*Wisconsin:* Wis. Stat. § 49.49.

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<sup>3</sup> These citations were taken from Robert Fabrikant, Paul E. Kalb, M.D., Mark D. Hopson, Pamela H. Bucy, Health Care Fraud: Enforcement and Compliance § 2.03[2] (Law Journal Press 2001).

## **APPENDIX B**

### **E-8.03 Conflicts of Interest: Guidelines**

Under no circumstances may physicians place their own financial interests above the welfare of their patients. The primary objective of the medical profession is to render service to humanity; reward or financial gain is a subordinate consideration. For a physician to unnecessarily hospitalize a patient, prescribe a drug, or conduct diagnostic tests for the physician's financial benefit is unethical. If a conflict develops between the physician's financial interest and the physician's responsibilities to the patient, the conflict must be resolved to the patient's benefit. (II) Issued July 1986; Updated June 1994.

### **E-8.054 Financial Incentives and the Practice of Medicine**

In order to achieve the necessary goals of patient care and to protect the role of physicians as advocates for individual patients, the following statement is offered for the guidance of physicians: (1) Although physicians have an obligation to consider the needs of broader patient populations within the context of the patient-physician relationship, their first duty must be to the individual patient. This obligation must override considerations of the reimbursement mechanism or specific financial incentives applied to a physician's clinical practice. (2) Physicians, individually or through their representatives, should evaluate the financial incentives associated with participation in a health plan before contracting with that plan. The purpose of the evaluation is to ensure that the quality of patient care is not compromised by unrealistic expectations for utilization or by placing that physician's payments for care at excessive risk. In the process of making judgments about the ethical propriety of such reimbursement systems, physicians should refer to the following general guidelines: (a) Monetary incentives may be judged in part on the basis of their size. Large incentives may create conflicts of interest that can in turn compromise clinical objectivity. While an obligation has been established to resolve financial conflicts of interest to the benefit of patients, it is important to recognize that sufficiently large incentives can create an untenable position for physicians; and (b) the proximity of large financial incentives to individual treatment decisions should be limited in order to prevent physicians' personal financial concerns from creating a conflict with their role as individual patient advocates. When the proximity of incentives cannot be mitigated, as in the case of fee-for-service payments, physicians must behave in accordance with prior Council recommendations limiting the potential for abuse. This includes the Council's prohibitions on fee-splitting arrangements, the provision of unnecessary services, unreasonable fees, and self-referral. For incentives that can be distanced from clinical decisions, physicians should consider the following factors in order to evaluate the correlation between individual act and monetary reward or penalty: (i) In general, physicians should favor incentives that are applied across broad physician groups. This dilutes the effect any one physician can have on his or her financial situation through clinical recommendations, thus allowing physicians to provide those services they feel are necessary in each case. Simultaneously, however, physicians are encouraged by the incentive to practice efficiently. (ii) The size

of the patient pool considered in calculations of incentive payments will affect the proximity of financial motivations to individual treatment decisions. The laws of probability dictate that in large populations of patients, the overall level of utilization remains relatively stable and predictable. Physicians practicing in plans with large numbers of patients in a risk pool therefore have greater freedom to provide the care they feel is necessary based on the likelihood that the needs of other plan patients will balance out decisions to provide extensive care. (iii) Physicians should advocate for the time period over which incentives are determined to be long enough to accommodate fluctuations in utilization resulting from the random distribution of patients and illnesses. For example, basing incentive payments on an annual analysis of resource utilization is preferable to basing them on monthly review. (iv) Financial rewards or penalties that are triggered by specific points of utilization may create enormous incentives as a physician's practice approaches the established level. Therefore, physicians should advocate that incentives be calculated on a continuum of utilization rather than a bracketed system with tiers of widely varied bonuses or penalties. (v) Physicians should ascertain that a stop-loss plan is in place to prevent the costs associated with unusual outliers from significantly impacting the reward or penalty offered to a physician. (3) Physicians also should advocate for incentives that promote efficient practice, but are not be designed to realize cost savings beyond those attainable through efficiency. As a counterbalance to the focus on utilization reduction, physicians also should advocate for incentives based on quality of care and patient satisfaction. (4) Patients must be informed of financial incentives that could impact the level or type of care they receive. Although this responsibility should be assumed by the health plan, physicians, individually or through their representatives, must be prepared to discuss with patients any financial arrangements that could impact patient care. Physicians should avoid reimbursement systems that, if disclosed to patients, could negatively affect the patient-physician relationship. (II, III) Issued June 1998 based on the report "Financial Incentives and the Practice of Medicine," adopted December 1997; updated June 2002.

### **E-8.06 Prescribing and Dispensing Drugs and Devices**

(1) Physicians should prescribe drugs, devices, and other treatments based solely upon medical considerations and patient need and reasonable expectations of the effectiveness of the drug, device or other treatment for the particular patient. (2) Physicians may not accept any kind of payment or compensation from a drug company or device manufacturer for prescribing its products. Furthermore, physicians should not be influenced in the prescribing of drugs, devices, or appliances by a direct or indirect financial interest in a firm or other supplier, regardless of whether the firm is a manufacturer, distributor, wholesaler, or repackager of the products involved. (3) Physicians may own or operate a pharmacy, but generally may not refer their patients to the pharmacy. Exceptionally, a physician may refer patients to his or her pharmacy in accord with guidelines established in Opinion 8.032, "Conflicts of Interest: Health Facility Ownership by a Physician." Physicians may dispense drugs within their office practices provided such dispensing primarily benefits the patient. (4) In all instances, physicians should respect the patient's freedom of choice in selecting who will fill their prescriptions as they are in the choice of a physician and, therefore, have the right to have

a prescription filled wherever they wish. (See Opinions 9.06, "Free Choice," and 8.03, "Conflicts of Interest: Guidelines.") Physicians should not urge patients to fill prescriptions from an establishment which has entered into a business or other preferential arrangement with the physician with respect to the filling of the physician's prescriptions. (5) A third party's offer to indemnify a physician for lawsuits arising from the physician's prescription or use of the third party's drug, device, or other product, introduces inappropriate incentives into medical decision making. Such offers, regardless of their limitations, therefore constitute unacceptable gifts. This does not address contractual assignments of liability between employers or in research arrangements, nor does it address government indemnification plans. (6) Patients have an ethically and legally recognized right to prompt access to the information contained in their individual medical records. Since a prescription is part of the patient's medical record, the patient is entitled to a copy of the physician's prescription for drugs or devices, including eyeglasses and contact lenses. Therefore, physicians should not discourage patients from requesting a written copy of a prescription. (II, III, IV, V) Issued June 2002. This opinion is a consolidation of previous Opinions 6.04, "Fee Splitting: Drug or Device Prescription Rebates;" 8.06, "Drugs and Devices: Prescribing;" and 8.07, "Gifts to Physicians: Offers of Indemnity."

### **E-8.13 Managed Care**

The expansion of managed care has brought a variety of changes to medicine including new and different reimbursement systems for physicians with complex referral restrictions and benefits packages for patients. Some of these changes have raised concerns that a physician's ability to practice ethical medicine will be adversely affected by the modifications in the system. In response to these concerns, the following points were developed to provide physicians with general guidelines that will assist them in fulfilling their ethical responsibilities to patients given the changes heralded by managed care. (1) The duty of patient advocacy is a fundamental element of the patient-physician relationship that should not be altered by the system of health care delivery. Physicians must continue to place the interests of their patients first. (2) When health care plans place restrictions on the care that physicians in the plan may provide to their patients, physicians should insist that the following principles be followed: (a) Any broad allocation guidelines that restrict care and choices--which go beyond the cost/benefit judgments made by physicians as a part of their normal professional responsibilities--should be established at a policy-making level so that individual physicians are not asked to engage in bedside rationing. (b) Regardless of any allocation guidelines or gatekeeper directives, physicians must advocate for any care they believe will materially benefit their patients. (c) Physicians should be given an active role in contributing their expertise to any allocation process and should advocate for guidelines that are sensitive to differences among patients. Health care plans should create structures similar to hospital medical staffs that allow physicians to have meaningful input into the plan's development of allocation guidelines. Guidelines for allocating health care should be reviewed on a regular basis and updated to reflect advances in medical knowledge and changes in relative costs. (d) Adequate appellate mechanisms for both patients and physicians should be in place to address disputes regarding medically necessary care. In some

circumstances, physicians have an obligation to initiate appeals on behalf of their patients. Cases may arise in which a health plan has an allocation guideline that is generally fair but in particular circumstances results in unfair denials of care, i.e., denial of care that, in the physician's judgment, would materially benefit the patient. In such cases, the physician's duty as patient advocate requires that the physician challenge the denial and argue for the provision of treatment in the specific case. Cases may also arise when a health plan has an allocation guideline that is generally unfair in its operations. In such cases, the physician's duty as patient advocate requires not only a challenge to any denials of treatment from the guideline but also advocacy at the health plan's policy-making level to seek an elimination or modification of the guideline. Physicians should assist patients who wish to seek additional, appropriate care outside the plan when the physician believes the care is in the patient's best interests. (e) Health care plans must adhere to the requirement of informed consent that patients be given full disclosure of material information. Full disclosure requires that health care plans inform potential subscribers of limitations or restrictions on the benefits package when they are considering entering the plan. (f) Physicians also should continue to promote full disclosure to patients enrolled in health care plans. The physician's obligation to disclose treatment alternatives to patients is not altered by any limitations in the coverage provided by the patient's health care plan. Full disclosure includes informing patients of all of their treatment options, even those that may not be covered under the terms of the health care plan. Patients may then determine whether an appeal is appropriate, or whether they wish to seek care outside the plan for treatment alternatives that are not covered. (g) Physicians should not participate in any plan that encourages or requires care below minimum professional standards. (3) When physicians are employed or reimbursed by health care plans that offer financial incentives to limit care, serious potential conflicts are created between the physicians' personal financial interests and the needs of their patients. Efforts to contain health care costs should not place patient welfare at risk. Thus, physicians should accept only those financial incentives that promote the cost-effective delivery of health care and not the withholding of medically necessary care. (a) Physicians should insist that any incentives to limit care must be disclosed fully to patients by plan administrators upon enrollment and at least annually thereafter. (b) Physicians should advocate that limits be placed on the magnitude of fee withholds, bonuses, and other financial incentives to limit care and that incentive payments be calculated according to the performance of a sizable group of physicians rather than on an individual basis. (c) Physicians should advocate that health care plans or other groups develop financial incentives based on quality of care. Such incentives should complement those based on the quantity of services used. (4) Physicians should encourage both that patients be aware of the benefits and limitations of their health care coverage and that they exercise their autonomy by public participation in the formulation of benefits packages and by prudent selection of health care coverage that best suits their needs. (I, II, III, V) Issued June 1996 based on the report "Ethical Issues in Managed Care," adopted June 1994 (JAMA. 1995; 273: 330-35); Updated June 2002.

### **E-8.135 Cost Containment Involving Prescription Drugs in Health Care Plans**

When health care plans, whether publicly or privately financed, establish drug formulary systems, physicians are obligated to advocate for formularies that meet the medical needs of their patients. (1) Physicians should maintain awareness of plan decisions about drug selection by staying informed, where appropriate, about pharmacy and therapeutics (P&T) committee actions and by ongoing personal review of formulary composition. P&T committee members should include independent physician representatives. Mechanisms should be established for ongoing peer review of formulary policy. Physicians who perceive inappropriate influences on formulary development should notify the proper regulatory authorities. (2) When scientifically based evidence is available, physicians are ethically required to advocate for changes to the formulary that would benefit the patient. Physicians also should advocate for exceptions to the formulary on a case-by-case basis when justified by the health care needs of particular patients. Mechanisms to appeal formulary exclusions should be established. Other cost-containment mechanisms, including prescription caps and prior authorization, should not unduly burden physicians or patients in accessing optimal drug therapy. Quality improvement rather than cost containment should be the primary determinant for formulary exclusions. In order to be cost efficient, however, physicians should select the lowest cost medication of equal efficacy for their patients. (3) Physicians should advocate that limits be placed on the extent to which health care plans use incentives or pressures to lower prescription drug costs. Financial incentives are permissible when they promote cost-effectiveness, not when they require withholding medically necessary care. Physicians should not be made to feel that they jeopardize their compensation or participation in a health care plan if they prescribe drugs that are necessary for their patients but that may also be costly. There should be limits on the magnitude of financial incentives, which should be calculated according to the practices of a sizeable group of physicians rather than on an individual basis, and incentives based on quality of care rather than cost of care should be used. Prescriptions should not be changed without the physician's knowledge and authorization. This affords the physician the opportunity to discuss the change with the patient. (4) Physicians should encourage health care plans to develop mechanisms to educate and assist physicians in cost-effective prescribing practices, including the availability of clinical pharmacists. Such initiatives are preferable to financial incentives or pressures by health care plans or hospitals, which can be ethically problematic. (5) Physicians should advocate that methods to limit prescription drug costs within health care plans in which they participate be disclosed to patients. In particular, they should encourage health care plans to inform patients upon enrollment concerning: (i) the existence of formularies (ii) provisions for cases in which the physician prescribes a drug that is not included in the formulary (iii) incentives or other mechanisms used to encourage formulary compliance by physicians (iv) relationships with pharmaceutical benefit management companies or pharmaceutical companies that could influence the composition of the formulary

If physicians exhaust all avenues to secure a formulary exception for a significantly advantageous drug, they are still obligated to disclose the option of the more beneficial drug to the patient, so that the patient can consider whether to obtain the medication out-

of-plan. Under circumstances in which the health care program will not subsidize the drug, physicians should help patients by identifying alternative forms of financial assistance, such as those available through pharmaceutical companies' assistance programs. (III) Issued June 1996 based on the report "Managed Care Cost Containment Involving Prescription Drugs," adopted June 1995 (Food and Drug Law Journal. 1998; 53: 25-34); updated June 2002.