

2012 SAEM ETHICS CURRICULUM

Module 11: Relationships with Industry

Primary Authors: Scott Kurpiel, MD and Joel Moll, MD FACEP
Department of Emergency Medicine, Emory University

ACGME EM Milestones:

- *PROF1: (Professional values)*
- *PROF2: (Accountability)*
- *SBP2: (Systems-based management; cost effective care)*
- *SBP3: (Technology: use effectively and ethically)*

Review 6/2012

11.1 Relationships with the Pharmaceutical Industry

11.2 Relationships with third party payers and other industry

11.1. Relationships with the Pharmaceutical Industry

Objectives:

1. Understand common goals and potential conflicts of interest between physicians and the pharmaceutical industry.
2. Consider the influence of industries' promotional activity on medical decision-making and patient care.
3. Review an approach to ethical considerations for interactions with pharmaceutical representatives and their promotional activity.

Case Study 11.1.a: Pharmaceutical sponsored free dinner and gift

You are invited to attend an educational session about the new treatment for patients who have suffered stroke. The session is sponsored by a pharmaceutical company that manufactures a thrombolytic agent. The session is in the evening at one of the best local restaurants. The company will pay the cost of the dinner and pay each physician in attendance two hundred dollars for his or her time.

Case Study 11.1.a: Questions:

1. What ethical considerations should be considered when deciding if you should agree to this arrangement?
2. Would the decision be different if the company had requested your department's administrative staff to arrange for physicians in your group to attend?

Background Information

The relationship between physicians and the pharmaceutical industry is complex. Physicians and industry share the common goal of improving human health and patient care, but industry has the additional responsibility to promote their product with the hopes to maximize investment-return for their shareholders. Drug companies' responsibility to act in the best interest of its shareholders to maximize return on investment creates the potential for an irreconcilable difference in values compared to physicians. Doctors must act ethically and professionally to prioritize care, advocacy and protection of their patients. The potential for conflict of interest from pharmaceutical marketing and the influence of promotional activity represents a threat to professionalism of individual physicians and their sponsoring institutions.

The pharmaceutical industry invests billions of dollars annually to discover new medicines, \$30.5 billion reported in 2001. Additionally, the pharmaceutical industry spends billions on product promotion and marketing, equating to \$8,000- \$13,000 spent directly or indirectly on physicians each year (Kowalenko et al, 2009). While major benefits result from pharmaceutical's research and development, their promotional activity has been proven to influence medical decision-making and physicians decision maker are not fully aware of their impact. Several studies show that physicians are more likely to prescribe drugs when they accept gifts and they are less likely to believe that such interactions affect their prescribing behavior. (Katz, 2003)

Interaction with the pharmaceutical industry is extremely common. The interaction can take the form of financial support for educational programs, industry-sponsored research, and social events. Clinical departments often accept and will seek promotional support, justified by operational budgetary constraints. Based on national surveys up to 94% of a sampling of physicians across all specialties having some interaction with industry. In a survey performed on academic emergency physicians, 84% reported an industry interaction, most commonly in the form of gifts or food in the workplace, and concludes that interactions that involved the exchange of money are more common with increasing academic rank (Birkhahn, 2008).

Academic faculty help to shape clinical practice and culture and should behave as role models when interfacing with the pharmaceutical industry. They produce practical guidelines, conduct research, and generate manuscripts and editorials. Values are transmitted to students and residents in the form of the educational process relative to all manner of professional relationships within the institution. Trainees learn in part by observing faculty behavior, and may model the manner of their professional relationships when interacting with industry.

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Professionalism is a core ethical principle to consider and when interacting with the pharmaceutical industry. Professionalism is an expression of the standards that guide the relationships in which physicians are engaged. Institutions have increasingly adopted and implemented policies that address specific interactions with industry and define the extent of what interactions are prohibited. These policies serve as a guide to limit pharmaceutical promotional activities to those that serve a genuine educational function that primarily entail a benefit to patients and emphasize objective scientific evidence with the opportunity for critical evaluation. Policies aim to maximize the beneficial mutual interaction while avoiding undue bias. It's the responsibility of the individual physician to familiarize themselves with their institutional policies and behave in accordance with these guidelines. When guidelines are lacking, physicians should navigate pharmaceutical relationships professionally by maintaining an awareness of the potential for bias in their medical decision-making and focusing on patient-centered evidenced based practice.

Gifts present another challenge. The American Medical Association has taken the stance that gifts accepted by physicians should primarily benefit patients and not be of substantial monetary value (AMA, 2011). Social sciences research shows that behavior can be influenced by gifts of negligible value by engaging the human tendency to interact within networks of obligation with reciprocation (Katz, 2003). Medication samples, if permitted, should be centrally managed to ensure timely patient access to optimal treatments. There may also be state-specific legal responsibilities when distributing and prescribing medications.

Full disclosure of all pertinent financial relationships is a key foundation to keep educational presentations fair and impartial. Potential conflicts of interests, even if there are no disclosures, should be formally acknowledged at the beginning of presentations. Lectures on pharmaceuticals should use generic nomenclature and demonstrate a comparison of comparable agents. The emphasis on transparency with full disclosure also applies to research endeavors. Academic centers should establish central oversight of requests and receipt of industry funding in the spirit of transparency.

Lastly, curriculum standards and educational material should be available to physicians at all levels of training covering drug discovery, development, clinical testing, safety, and regulation. Curricula can include education on critical thinking including understanding of how promotional activities can influence decision-making and how to consider cost-benefit analysis as a component of prescribing practice.

Ultimately, the public and patients entrust their physicians to provide them with optimal care. The interest in preserving complete and unbiased medical knowledge is a driving force in avoiding and eliminating inappropriate pharmaceutical promotional activities.

11.2. Relationships with third party payers and other industry

Objectives:

1. Understand potential conflicts of interest between third party payers and legal requirements
 2. Review potential conflicts between physician's medical opinion and desires to ensure coverage for their patient's emergency department visit
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Case Study 11.2.a: HMO denies pediatric emergency department visit

A 4 month old previously healthy full term infant is brought to the ED by her mother for a fever. Triage contacts her HMO who declines the ED visit and directs her to her pediatrician's office instead. The triage nurse asks you if the child should be registered or allowed to proceed to her pediatrician's office to wait as a walk in patient.

Case Study 11.2.a: Questions:

1. What is your obligation as an emergency physician to this patient?
 2. Does knowing that the insurance company has denied the ED visit change your approach in evaluation, or extent of testing?
 3. Do you notify the mother that the insurance may not cover the visit before seeing the child?
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Background Information

Although the influence of pharmaceutical industry often takes the forefront in the context of ethical considerations with industry relations for the emergency physician, sometimes conflicts can occur with managed care and third party payers as well. The Emergency Medicine Treatment and Active Labor Act (EMTALA) passed by Congress in 1986 requires hospitals to provide a medical screening exam to determine if an emergency medical condition exists, and if so to provide stabilization of that condition. Many states have also enacted similar statutes that may further define or expand the responsibility of the emergency department. Medicare and Medicaid have provisions that do not require preauthorization for payment of emergency visits for enrolled patients, however this may not be the case for private insurers. Some third party payers, especially in the setting of managed care, require preauthorization, which is in conflict with EMTALA. This is especially true considering the provision specifies not to delay the medical screening exam and treatment to determine the patient's ability to pay.

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EMTALA is essentially an unfunded mandate in the case of third party payers. Hospitals should develop process and policies that address and resolve such conflicts, or do so in their contracts with third party payers. Emergency physicians should be aware of the policy and process where they practice. Ultimately, providing a medical screening exam regardless of patient's ability to pay is the ethically sound and mandated legal obligation.

Emergency physicians may also find themselves with ethical conflicts relating to payment for their services. Since third party payers do not have a responsibility under EMTALA to cover emergency department costs, third party payers have declined payment for services, especially if an emergency medical condition in their view was not found. This has led to advocacy in many states and the development of prudent layperson legislation. Such legislation requires that third party payors pay for emergency department treatment for certain conditions or complaints that most people would consider an emergency. Specifically someone who possesses an average knowledge of health and medicine, and insurance coverage is based not on ultimate diagnosis, but on whether a prudent person might anticipate serious impairment to his or her health in such an emergency situation. Medicare and Medicaid included a prudent layperson requirement in the Balanced Budget Act of 1997 and extended it to all federal workers plans in 1999. Most states have a form of prudent layperson legislation at present. The Patient Bill of Rights passed as part of national health care reform in 2010 provides a national prudent layperson standard. However recent economic and budgetary challenges have in some cases reopened whether such visits should be covered or limited to contain the rising cost of healthcare. This has been vigorously opposed by emergency medicine advocacy and professional organizations. American College of Emergency Physician (ACEP) policy states: "Gatekeeping activities that threaten patient safety are unethical, as are clauses that prevent physicians from informing patients about reasonable treatment alternatives." Although there is a financial incentive for emergency physicians to be able to collect payment in the support of such measures, which can be seen as a potential conflict of interest, the public health benefits of allowing reasonable access to emergency care are paramount and overriding.

Even under the circumstances where prudent layperson legislation is in effect, physicians may sometimes feel conflicted to manipulate diagnosis or exaggerate clinical situations in order to allow patients access to care or increase the likelihood of reimbursement for performed care that might otherwise be denied. A study by Wynia et al in 2000 reported that 39% of physicians surveyed reported exaggerating the severity of the patients condition, changing the billing diagnosis, or reporting signs and symptoms that the patient did not have in order to arrange care for which the patient may not otherwise qualify. Although this has not been studied specifically in emergency physicians, it is fair to say such situations probably arise in emergency medicine as well. We as emergency physicians are ultimately patient advocates, and are used to advocating dispositions and care for our patients to our consultants and others. However it is important in our advocacy is patient centric, had no financial benefit to our personal interests, is reasonable, and not overtly fraudulent.

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There are many other situations involving physician employment status, personal financial interests, or other industry relationships that may occur for the emergency physician. Emergency physician employment takes a varied and often changing form and is far from ubiquitous or standard. In dealing with relations with industry and potential conflicts of interest that arise, being the patients advocate and putting their health and interest first will lead to true patient centered and ethical emergency care.

Bibliography:

American Academy of Emergency Medicine. Position statement on managed care. Available at: <http://www.aaem.org/positionstatements/managedcare.php> Accessed December 10, 2011.

American College of Emergency Physicians. Relationships with business and administration. Available at: <http://www.acep.org/Content.aspx?id=29144>. Accessed December 10, 2011.

American Medical Association Code of Medical Ethics. Opinion 8.061 – Gifts to Physicians from Industry. Available at: <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion8061.page>. Accessed Dec 10, 2011.

Birkhahn RH, Jauch E, Kramer DA, et al. Academic emergency medicine faculty and industry relationships. *Acad Emerg Med*. 2008; 15: 819-824.

Brennan TA, Rothman DJ, Blank L, et al. Health industry practices that create conflicts of interest: a policy proposal for academic medical centers. *JAMA*. 2006; 295: 429-433.

Fedor FP, Perez AM. Resolving conflicts between EMTALA and managed care requirements. *Healthc Financ Manage*. 2001; 55(9): 46-49.

Katz D, Caplan AL, Merz JF. All gifts large and small: toward an understanding of the ethics of pharmaceutical industry gift-giving. *Am J Bioeth*. 2003; 3: 39-46.

Keim S, Perina D, on behalf of the CORD Board of Directors. Council of Emergency Medicine Residency Directors Position on Interactions between Emergency Medicine Residencies and the Pharmaceutical Industry, 2003. Available at: <http://www.cordem.org/i4a/pages/index.cfm?pageid=3343>. Accessed Dec 10, 2011.

Kowalenko T, Char D, Marco C, et al. Industry relations with emergency medicine graduate medical education programs. *Acad Emerg Med*. 2009; 16: 1025-1030.

Moskop JC, Iserson KV, Aswegan AL, Larkin GL, Schears RM. Gifts to physicians from industry: the debate evolves. *Ann Emerg Med*. 2012; 59: 89-97.

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Okike K, Kocher MS, Wei EX, Mehlman CT, Bhandari M. Accuracy of conflict-of-interest disclosures reported by physicians. *N Engl J Med*. 2009; 361: 1466-1474.

Schneider JA, Arora V, Kasza K, Van Harrison R, Humphrey H. Residents' perceptions over time of pharmaceutical industry interactions and gifts and the effect of an education intervention. *Acad Med*. 2006; 81: 595-602.

Studdert DM, Mello MM, Brennan TA. Financial conflicts of interest in physicians' relationships with pharmaceutical industry- self-regulation in the shadow of federal persecution. *N Engl J Med*. 2004; 18: 1891-1900.

Wazana A. Physician and the pharmaceutical industry: Is a gift ever just a gift? *JAMA*. 2000; 283(20): 373-380.

Weinfurt K, Friedman JY, Dinan MA, et al. Disclosing conflicts of interest in clinical research: views of the institutional review boards, conflicts of interest committees, and investigators. *J Law Med Ethics*. 2006; 34: 581-596.

Wynia MK, Cummins DS, VanGeest JB, Wilson IB. Physician manipulation of reimbursement rules for patients. *JAMA*. 2000; 283: 1858-1865.

Zinner DE, DesRoches CM, Fristol SJ, Clarridge B, Campbell EG. Tightening conflict-of-interest policies: the impact of 2005 ethics rules at the NIH. *Acad Med*. 2010; 85: 1685-1691.