AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 207
(I-19)

Introduced by: Medical Student Section

Subject: Pharmaceutical Advertising in Electronic Health Record Systems

Referred to: Reference Committee B

Whereas, In certain Electronic Health Records (EHR) systems, there exist subtle, yet noticeable advertisements for pharmaceutical drugs; and

Whereas, Pharmaceutical advertising in EHRs generally appears in the administrative, consultation, or prescribing interface of EHR software as text-based advertisements or image-based banners[1]; and

Whereas, Advertisements in EHRs can include various types of information, such as treatment suggestions, recommendations for drug initiation and titration protocols, common side effects of medications, formulary coverage information, pictures of devices, and clinical trial-based evidence of a drug's efficacy; and

Whereas, Advertisements can be targeted based on physician specialty, target list, geography, past prescribing behavior, patient demographic, current therapy, or patient diagnosis on ICD-10 codes[2]; and

Whereas EHR infrastructure raises the obvious concern of whether advertising viewed by a physician within an EHR either consciously or unconsciously influences the physician's treatment[3]; and

Whereas, Patients may receive suboptimal care if there is physician bias in prescribing medications or treatments advertised in EHRs[3]; and

Whereas, Advertisements may lead to overprescribing of medications or treatments advertised or under prescribing of a less heavily advertised drug with better efficacy or lower cost[3]; and

Whereas, There exist a variety of revenue models for EHR systems, including but not limited to upfront costs for software, pay-to-play, data selling and boutique services; and

Whereas, Pharmaceutical advertising can be aimed at either patients (direct to consumer or DTC) or at physicians (direct to physician); and

Whereas, DTC advertising is regulated by the Food and Drug Administration (FDA) Division of Drug Marketing, Advertising and Communications via the Federal Food, Drug and Cosmetic Act of 1938[7]; and

Whereas, In 1969 regulations were passed specifically addressing pharmaceutical advertising to physicians, stating that ads may not be false or misleading, must present balanced

information of risks and benefits, include facts that are essential to the product's advertised uses, and must present a brief summary that mentions every risk in the product labeling[8]; and

Whereas, In 2002, the Secretary of Health and Human Services (HHS) passed a ruling that required all draft regulatory letters be reviewed by the FDA's office of chief counsel before they were sent to pharmaceutical companies, resulting in a decrease of warning letters[9]; and

Whereas, The AMA has nuanced existing policy regarding pharmaceutical companies' interactions with physicians; and

Whereas, The AMA recognizes that pharmaceutical marketing can unethically influence physicians and endanger the patient/physician relationship if done inappropriately, but when done appropriately may provide benefits to patients; and

Whereas, Existing AMA policies outline that pharmaceutical influence is only acceptable through certain avenues, and that the point of care deserves special consideration; and

Whereas, These existing policies underscore that pharmaceutical advertising with the potential to bias physicians must provide a benefit to the patient in order to be acceptable; and

Whereas, A 2013 review by Manchanda and Honka concludes that detailing (personal advertisement or sales of drugs to physicians by pharmaceutical sales representatives) does change physician prescribing practices in the short-term, however, there is not enough data to conclude whether these prescribing decisions positively or negatively affect patient health outcomes, or how large this effect my be[10]; and

Whereas, The U.S. Food and Drug Administration is limited in their oversight of pharmaceutical advertising practices that may unduly affect patient health and may lack sufficient resources to even complete the regulatory activities that are contained within their mandate; therefore be it

RESOLVED, That our American Medical Association encourage the Centers for Medicare and Medicaid Services to study the effects of direct-to-physician advertising at the point of care, including advertising in Electronic Health Record Systems (EHRs), on physician prescribing, patient safety, health care costs, and EHR access for small practices (Directive to Take Action); and be it further

RESOLVED, That our AMA study the ethics of direct-to-physician advertising at the point of care, including advertising in EHRs. (Directive to Take Action)

Fiscal Note: not yet determined

Date Received: 10/01/19

References:

1. Sporrer L, Bogus S. April 2018. https://www.cmimedia.com/insights/povs/electronic-health-records-and-pharmaceutical-advertising. Accessed February 18, 2019.
2. CMI-Compas-Whitepaper-EHRs-April-2018.pdf. https://www.cmimedia.com/wp-content/uploads/2018/04/CMI-Compas-Whitepaper-EHRs-April-2018.pdf. Accessed February 17, 2019.
3. Harvey K. (PDF) Pharmaceutical advertisements in prescribing software: An analysis. https://www.researchgate.net/publication/7721362_Pharmaceutical_advertisements_in_prescribing_software_An_analysis. Accessed March 24, 2019.
4. Liu. Epic Systems: EMR company isn't as epic as it thinks it is. https://openforum.hbs.org/challenge/understand-digital-transformation-of-business/why-digital/epic-systems-emr-company-isn-t-as-epic-as-it-thinks-it-is. Accessed March 24, 2019.
5. If an EHR Company's Business Model Can Be Beautiful, Hello Health May Be Hard to Turn Away From - Electronic Health Reporter. https://electronichealthreporter.com/ehr-companys-business-model-beautiful-health-hard-turn/. Accessed March 24, 2019.

6. EHRIntelligence. Practice Fusion No Longer Offering Free EHR System Software. EHRIntelligence. https://ehrintelligence.com/news/practice-fusion-no-longer-offering-free-ehr-system-software. Published February 23, 2018. Accessed March 24, 2019.
7. CFR - Code of Federal Regulations Title 21. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=202&showFR=1. Accessed February 17, 2019.
8. Research C for DE and. Warning Letters and Notice of Violation Letters to Pharmaceutical Companies - Warning Letters 2018. https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCcompanies/ucm594437.htm. Accessed March 14, 2019.
9. Ventola CL. Direct-to-Consumer Pharmaceutical Advertising. *Pharm Ther*. 2011;36(10):669-684.
10. Manchanda P, Honka E. The Effects and Role of Direct-to-Physician Marketing in the Pharmaceutical Industry: An Integrative Review. *Yale J Health Policy Law Ethics*. 5(2). https://digitalcommons.law.yale.edu/yjhple/vol5/iss2/8.
11. Manchanda P, Chintagunta P. Responsiveness of Physician Prescription Behavior to Salesforce Effort: An Individual Level Analysis. *Mark Lett*. 2004;15(2-3):129-145. doi:https://doi-org.libproxy.unm.edu/10.1023/B:MARK.0000047389.93584.09
12. Van Zee A. The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy. *Am J Public Health*. 2009;99(2):221-227. doi:10.2105/AJPH.2007.131714

RELEVANT AMA POLICY

Support of American Drug Industry H-100.995
Our AMA continues to support the American pharmaceutical manufacturing industry in its efforts to develop and market pharmaceutical products meeting proper standards of safety and efficacy for the benefit of the American people.
Citation: (Sub. Res. 20, A-74; Reaffirmed: CLRPD Rep. C, A-89; Reaffirmed: Sunset Report, A-00; Reaffirmed: CSAPH Rep. 1, A-10)

Direct-to-Consumer Advertising (DTCA) of Prescription Drugs and Implantable Devices H-105.988
1. To support a ban on direct-to-consumer advertising for prescription drugs and implantable medical devices.
2. That until such a ban is in place, our AMA opposes product-claim DTCA that does not satisfy the following guidelines:
(a) The advertisement should be indication-specific and enhance consumer education about the drug or implantable medical device, and the disease, disorder, or condition for which the drug or device is used.
(b) In addition to creating awareness about a drug or implantable medical device for the treatment or prevention of a disease, disorder, or condition, the advertisement should convey a clear, accurate and responsible health education message by providing objective information about the benefits and risks of the drug or implantable medical device for a given indication. Information about benefits should reflect the true efficacy of the drug or implantable medical device as determined by clinical trials that resulted in the drug's or device's approval for marketing.
(c) The advertisement should clearly indicate that the product is a prescription drug or implantable medical device to distinguish such advertising from other advertising for non-prescription products.
(d) The advertisement should not encourage self-diagnosis and self-treatment, but should refer patients to their physicians for more information. A statement, such as "Your physician may recommend other appropriate treatments," is recommended.
(e) The advertisement should exhibit fair balance between benefit and risk information when discussing the use of the drug or implantable medical device product for the disease, disorder, or condition. The amount of time or space devoted to benefit and risk information, as well as its cognitive accessibility, should be comparable.
(f) The advertisement should present information about warnings, precautions, and potential adverse reactions associated with the drug or implantable medical device product in a manner (e.g., at a reading grade level) such that it will be understood by a majority of consumers, without distraction of content, and will help facilitate communication between physician and patient.
(g) The advertisement should not make comparative claims for the product versus other prescription drug or implantable medical device products; however, the advertisement should include information about the availability of alternative non-drug or non-operative management options such as diet and lifestyle changes, where appropriate, for the disease, disorder, or condition.
(h) In general, product-claim DTCA should not use an actor to portray a health care professional who promotes the drug or implantable medical device product, because this portrayal may be misleading and deceptive. If actors portray health care professionals in DTCA, a disclaimer should be prominently displayed.
(i) The use of actual health care professionals, either practicing or retired, in DTCA to endorse a specific drug or implantable medical device product is discouraged but if utilized, the advertisement must include a clearly visible disclaimer that the health care professional is compensated for the endorsement.
(j) The advertisement should be targeted for placement in print, broadcast, or other electronic media so as to avoid audiences that are not age appropriate for the messages involved.

(k) In addition to the above, the advertisement must comply with all other applicable Food and Drug Administration (FDA) regulations, policies and guidelines.
3. That the FDA review and pre-approve all DTCA for prescription drugs or implantable medical device products before pharmaceutical and medical device manufacturers (sponsors) run the ads, both to ensure compliance with federal regulations and consistency with FDA-approved labeling for the drug or implantable medical device product.
4. That the Congress provide sufficient funding to the FDA, either through direct appropriations or through prescription drug or implantable medical device user fees, to ensure effective regulation of DTCA.
5. That DTCA for newly approved prescription drug or implantable medical device products not be run until sufficient post-marketing experience has been obtained to determine product risks in the general population and until physicians have been appropriately educated about the drug or implantable medical device. The time interval for this moratorium on DTCA for newly approved drugs or implantable medical devices should be determined by the FDA, in negotiations with the drug or medical device product's sponsor, at the time of drug or implantable medical device approval. The length of the moratorium may vary from drug to drug and device to device depending on various factors, such as: the innovative nature of the drug or implantable medical device; the severity of the disease that the drug or implantable medical device is intended to treat; the availability of alternative therapies; and the intensity and timeliness of the education about the drug or implantable medical device for physicians who are most likely to prescribe it.
6. That our AMA opposes any manufacturer (drug or device sponsor) incentive programs for physician prescribing and pharmacist dispensing that are run concurrently with DTCA.
7. That our AMA encourages the FDA, other appropriate federal agencies, and the pharmaceutical and medical device industries to conduct or fund research on the effect of DTCA, focusing on its impact on the patient-physician relationship as well as overall health outcomes and cost benefit analyses; research results should be available to the public.
8. That our AMA supports the concept that when companies engage in DTCA, they assume an increased responsibility for the informational content and an increased duty to warn consumers, and they may lose an element of protection normally accorded under the learned intermediary doctrine.
9. That our AMA encourages physicians to be familiar with the above AMA guidelines for product-claim DTCA and with the Council on Ethical and Judicial Affairs Ethical Opinion E-9.6.7 and to adhere to the ethical guidance provided in that Opinion.
10. That the Congress should request the Agency for Healthcare Research and Quality or other appropriate entity to perform periodic evidence-based reviews of DTCA in the United States to determine the impact of DTCA on health outcomes and the public health. If DTCA is found to have a negative impact on health outcomes and is detrimental to the public health, the Congress should consider enacting legislation to increase DTCA regulation or, if necessary, to prohibit DTCA in some or all media. In such legislation, every effort should be made to not violate protections on commercial speech, as provided by the First Amendment to the U.S. Constitution.
11. That our AMA supports eliminating the costs for DTCA of prescription drugs as a deductible business expense for tax purposes.
12. That our AMA continues to monitor DTCA, including new research findings, and work with the FDA and the pharmaceutical and medical device industries to make policy changes regarding DTCA, as necessary.
13. That our AMA supports "help-seeking" or "disease awareness" advertisements (i.e., advertisements that discuss a disease, disorder, or condition and advise consumers to see their physicians, but do not mention a drug or implantable medical device or other medical product and are not regulated by the FDA).
14. Our AMA will advocate to the applicable Federal agencies (including the Food and Drug Administration, the Federal Trade Commission, and the Federal Communications Commission) which regulate or influence direct-to-consumer advertising of prescription drugs that such advertising should be required to state the manufacturer’s suggested retail price of those drugs.
Citation: BOT Rep. 38 and Sub. Res. 513, A-99; Reaffirmed: CMS Rep. 9, Amended: Res. 509, and Reaffirmation I-99; Appended & Reaffirmed: Sub. Res. 503, A-01; Reaffirmed: Res. 522, A-02; Reaffirmed: Res. 914, I-02; Reaffirmed: Sub. Res. 504, A-03; Reaffirmation A-04; Reaffirmation A-05; Modified: BOT Rep. 9, A-06; Reaffirmed in lieu of Res. 514, A-07; BOT Action in response to referred for decision: Res. 927, I-15; Modified: BOT Rep. 09, I-16; Appended: Res. 236, A-17; Reaffirmed in lieu of: Res. 223, A-17; Reaffirmed in lieu of: Res. 112, A-19;

E-9.6.7 Direct-to-Consumer Advertisement of Prescription Drugs
Direct-to-consumer advertising may raise awareness about diseases and treatment and may help inform patients about the availability of new diagnostic tests, drugs, treatments, and devices. However, direct-to-consumer advertising also carries the risk of creating unrealistic expectations for patients and conflicts of interest for physicians, adversely affecting patientshealth and safety, and compromising patient physician relationships.

In the context of direct-to-consumer advertising of prescription drugs, physicians individually should:
(a) Remain objective about advertised tests, drugs, treatments, and devices, avoiding bias for or against advertised products.
(b) Engage in dialogue with patients who request tests, drugs, treatments, or devices they have seen advertised to:
(i) assess and enhance the patients understanding of the test, drug or device;
(ii) educate patients about why an advertised test, drug, or device may not be suitable for them, including providing cost-effectiveness information about different options.
(c) Resist commercially induced pressure to prescribe tests, drugs, or devices that may not be indicated.
(d) Obtain informed consent before prescribing an advertised test, drug, or device, in keeping with professional standards.
(e) Deny requests for an inappropriate test, drug, or device.
(f) Consider reporting to the sponsoring manufacturer or appropriate authorities direct-to-consumer advertising that:
(i) promotes false expectations;
(ii) does not enhance consumer education;
(iii) conveys unclear, inaccurate, or misleading health education messages;
(iv) fails to refer patients to their physicians for additional information;
(v) does not identify the target population at risk;
(vi) encourages consumer self-diagnosis and treatment.
Collectively, physicians should:
(g) Encourage and engage in studies that examine the impact of direct-to-consumer advertising on patient health and medical care.
(h) Whenever possible, assist authorities to enforce existing law by reporting advertisements that do not:
(i) provide a fair and balanced discussion of the use of the drug product for the disease, disorder, or condition;
(ii) clearly explain warnings, precautions, and potential adverse reactions associated with the drug product;
(iii) present summary information in language that can be understood by the consumer
(iv) comply with applicable regulations;
(v) provide collateral materials to educate both physicians and consumers.
AMA Principles of Medical Ethics: II,III
The Opinions in this chapter are offered as ethics guidance for physicians and are not intended to establish standards of clinical practice or rules of law.
Issued: 2016

E-9.6.2 Gifts to Physicians from Industry
Relationships among physicians and professional medical organizations and pharmaceutical, biotechnology, and medical device companies help drive innovation in patient care and contribute to the economic well-being of the community to the ultimate benefit of patients and the public. However, an increasingly urgent challenge for both medicine and industry is to devise ways to preserve strong, productive collaborations at the same time that they take clear effective action to prevent relationships that damage public trust and tarnish the reputation of both parties.
Gifts to physicians from industry create conditions that carry the risk of subtly biasingor being perceived to biasprofessional judgment in the care of patients.
To preserve the trust that is fundamental to the patient-physician relationship and public confidence in the profession, physicians should:
(a) Decline cash gifts in any amount from an entity that has a direct interest in physicianstreatment recommendations.
(b) Decline any gifts for which reciprocity is expected or implied.
(c) Accept an in-kind gift for the physicians practice only when the gift:
(i) will directly benefit patients, including patient education; and
(ii) is of minimal value.
(d) Academic institutions and residency and fellowship programs may accept special funding on behalf of trainees to support medical students, residents, and fellowsparticipation in professional meetings, including educational meetings, provided:
(i) the program identifies recipients based on independent institutional criteria; and
(ii) funds are distributed to recipients without specific attribution to sponsors.
AMA Principles of Medical Ethics: II
The Opinions in this chapter are offered as ethics guidance for physicians and are not intended to establish standards of clinical practice or rules of law.
Issued: 2016

Sample Medications H-120.991
Our AMA (1) continues to support the voluntary time-honored practice of physicians providing drug samples to selected patients at no charge;
(2) reiterates that samples of prescription drug products represent valuable benefits to the patients;
(3) continues to support the availability of drug samples directly to physicians through manufacturers' representatives and other means, with appropriate safeguards to prevent diversion; and
(4) endorses sample practices that: (a) preclude the sale, trade or offer to sell or trade prescription drug samples; (b) require samples of prescription drug products to be distributed only to licensed practitioners upon written request; and (c) require manufacturers and commercial distributors of samples of prescription drug products and their representatives providing such samples to licensed practitioners to: (i) handle and store samples of prescription drug products in a manner to maintain potency and assure security; (ii) account for the distribution of prescription drug samples by maintaining records of all drug samples distributed, destroyed or returned to the manufacturer or distributor; and (iii) report significant thefts or losses of prescription drug samples.
Citation: (Sub. Res. 17, I-86; Reaffirmed: BOT Rep. 53, A-94; Reaffirmed: Res. 516, A-01; Reaffirmed: CSAPH Rep. 1, A-11)

E-9.2.7 Financial Relationships with Industry in Continuing Medical Education
In an environment of rapidly changing information and emerging technology, physicians must maintain the knowledge, skills, and values central to a healing profession. They must protect the independence and commitment to fidelity and service that define the medical profession.
Financial or in-kind support from pharmaceutical, biotechnology or medical device companies that have a direct interest in physicians recommendations creates conditions in which external interests could influence the availability and/or content of continuing medical education (CME). Financial relationships between such sources and individual physicians who organize CME, teach in CME, or have other roles in continuing professional education can carry similar potential to influence CME in undesired ways.
CME that is independent of funding or in-kind support from sources that have financial interests in physicians recommendations promotes confidence in the independence and integrity of professional education, as does CME in which organizers, teachers, and others involved in educating physicians do not have financial relationships with industry that could influence their participation. When possible, CME should be provided without such support or the participation of individuals who have financial interests in the educational subject matter.
In some circumstances, support from industry or participation by individuals who have financial interests in the subject matter may be needed to enable access to appropriate, high-quality CME. In these circumstances, physician-learners should be confident that vigorous efforts will be made to maintain the independence and integrity of educational activities.
Individually and collectively physicians must ensure that the profession independently defines the goals of physician education, determines educational needs, and sets its own priorities for CME. Physicians who attend CME activities should expect that, in addition to complying with all applicable professional standards for accreditation and certification, their colleagues who organize, teach, or have other roles in CME will:
(a) Be transparent about financial relationships that could potentially influence educational activities.
(b) Provide the information physician-learners need to make critical judgments about an educational activity, including:
(i) the source(s) and nature of commercial support for the activity; and/or
(ii) the source(s) and nature of any individual financial relationships with industry related to the subject matter of the activity; and
(iii) what steps have been taken to mitigate the potential influence of financial relationships.
(c) Protect the independence of educational activities by:
(i) ensuring independent, prospective assessment of educational needs and priorities;
(ii) adhering to a transparent process for prospectively determining when industry support is needed;
(iii) giving preference in selecting faculty or content developers to similarly qualified experts who do not have financial interests in the educational subject matter;
(iv) ensuring a transparent process for making decisions about participation by physicians who may have a financial interest in the educational subject matter;
(v) permitting individuals who have a substantial financial interest in the educational subject matter to participate in CME only when their participation is central to the success of the educational activity; the activity meets a demonstrated need in the professional community; and the source, nature, and magnitude of the individuals specific financial interest is disclosed; and
(vi) taking steps to mitigate potential influence commensurate with the nature of the financial interest(s) at issue, such as prospective peer review.
AMA Principles of Medical Ethics: I,V

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Issued: 2016

E-10.6 Industry Representatives in Clinical Settings
Representatives of medical device manufacturers can play an important role in patient safety and quality of care by providing information about the proper use of their companiesdevices or equipment and by offering technical assistance to physicians. However, allowing industry representative to be present in clinical settings while care is being given also raises concerns. Their presence can raise pose challenges for patient autonomy, privacy, and confidentiality as well as safety and professionalism in care-giving.
Physicians have a responsibility to protect patient interests and thus have a corresponding obligation to exercise good professional judgment in inviting industry representatives into the clinical setting. Physicians should recognize that in this setting appropriately trained industry representatives function as consultants. Participation by industry representatives should not be allowed to substitute for training physicians to use devices and equipment safely themselves.
Physicians who invite industry representatives into the clinical setting should ensure that:
(a) The representatives participation will improve the safety and effectiveness of patient care.
(b) The representatives qualifications to provide the desired assistance have been appropriately screened.
(c) The patient is aware that an industry representative will facilitate care, has been informed about the scope and nature of the representatives role in care, and has agreed to the representatives participation.
(d) The representative understands and is committed to upholding medical standards of respect for patient privacy and confidentiality.
(e) The representative has agreed to abide by the policies of the health care institution governing his or her presence and clinical activities.
(f) The representative does not exceed the bounds of his or her training, is adequately supervised, and does not engage in the practice of medicine.
AMA Principles of Medical Ethics: I,IV,V
The Opinions in this chapter are offered as ethics guidance for physicians and are not intended to establish standards of clinical practice or rules of law.
Issued: 2016

Use of Physician and Patient Prescribing Data in the Pharmaceutical Industry D-315.988
Our AMA will (1) work to control the use of physician-specific prescribing data by the pharmaceutical industry as follows: (a) implement a suitable "opt-out" mechanism for the AMA Physician Masterfile governing the release of physician-specific prescribing data to pharmaceutical sales reps by including appropriate restrictions in the AMA data licensing agreements; (b) communicate to physicians the resources available to them in reporting inappropriate behavior on the part of pharmaceutical sales representatives and the work the AMA has done and will continue to do on their behalf; and (c) work with Health Information Organizations (HIOs) to describe to physicians how their prescribing data are used and work to create access for physicians to view reports on their own prescribing data to enhance their clinical practice; and (2) assume a leadership position in both developing a Prescribing Data Code of Conduct for the Pharmaceutical Industry that dictates appropriate use of pharmaceutical data, behavior expectations on the part of industry, and consequences of misuse or misconduct, and in convening representatives from HIOs and the pharmaceutical companies to promulgate the adoption of the code of conduct in the use of prescribing data.
Citation: (BOT Rep. 24, I-04; Reaffirmed in lieu of Res. 624, A-05; Reaffirmation A-09; Reaffirmed: Res. 233, A-11)

Impact of Pharmaceutical Advertising on Women's Health D-105.996
1. Our AMA urges the US Food and Drug Administration (FDA) to assure that all direct-to-consumer advertising of pharmaceuticals includes information regarding differing effects and risks between the sexes.
2. Our AMA urges the FDA to assure that advertising of pharmaceuticals to health care professionals includes specifics outlining whether testing of drugs prescribed to both sexes has included sufficient numbers of women to assure safe use in this population and whether such testing has identified needs to modify dosages based on sex.
Citation: Res. 509, A-14;

Hospital Policies on Interactions with Industry H-225.948
1. Our AMA encourages all hospitals to adopt policies governing the interaction of hospital personnel--including both employed physicians and independent members of the medical staff, as well as other hospital staff--with pharmaceutical, medical device, and other industry representatives within the hospital setting. Such policies should: (a) be developed through a collaborative effort of the hospital's organized medical staff, administration,

and governing body, and approved by the organized medical staff; and (b) be consistent with applicable AMA policy and ethical opinions on the subject of medicine-industry interaction, including but not limited to:
E-1.001 Principles of Medical Ethics
E-5.0591 Patient Privacy and Outside Observers to the Clinical Encounter
E-8.03 Conflicts of Interest: Guidelines
E-8.031 Conflicts of Interest: Biomedical Research
E-8.0315 Managing Conflicts of Interest in the Conduct of Clinical Trials
E-8.047 Industry Representatives in Clinical Settings
E-8.06 Prescribing and Dispensing Drugs and Devices
E-8.061 Gifts to Physicians from Industry
E-9.0115 Financial Relationships with Industry in Continuing Medical Education
H-460.981 University-Industry Cooperative Research Ventures.
2. Our AMA will inform the American Hospital Association of the AMA's position on hospital policies governing the interaction of hospital personnel with pharmaceutical, medical device, and other industry representatives within the hospital setting.
Citation: (BOT Rep. 27, A-14)

E-3.2.4 Access to Medical Records by Data Collection Companies
Information contained in patients' medical records about physicians' prescribing practices or other treatment decisions can serve many valuable purposes, such as improving quality of care. However, ethical concerns arise when access to such information is sought for marketing purposes on behalf of commercial entities that have financial interests in physicianstreatment recommendations, such as pharmaceutical or medical device companies.
Information gathered and recorded in association with the care of a patient is confidential. Patients are entitled to expect that the sensitive personal information they divulge will be used solely to enable their physician to most effectively provide needed services. Disclosing information to third parties for commercial purposes without consent undermines trust, violates principles of informed consent and confidentiality, and may harm the integrity of the patient-physician relationship.
Physicians who propose to permit third-party access to specific patient information for commercial purposes should:
(a) Only provide data that has been de-identified.
(b) Fully inform each patient whose record would be involved (or the patients authorized surrogate when the individual lacks decision-making capacity) about the purpose(s) for which access would be granted.
Physicians who propose to permit third parties to access the patients full medical record should:
(c) Obtain the consent of the patient (or authorized surrogate) to permit access to the patient's medical record.
(d) Prohibit access to or decline to provide information from individual medical records for which consent has not been given.
(e) Decline incentives that constitute ethically inappropriate gifts, in keeping with ethics guidance.
AMA Principles of Medical Ethics: I,II,IV
The Opinions in this chapter are offered as ethics guidance for physicians and are not intended to establish standards of clinical practice or rules of law.
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