Conflict of Interest Policy Guide for Academic Medical Centers and Medical Schools

COMMUNITY CATALYST

COI Toolkit on Transparency and Disclosure

Transparency and Disclosure

Relationships of physicians, researchers, and medical institutions with the pharmaceutical, device, and biotechnology industry pose significant risks to medical professionalism and the mission of academic medical centers.[1] While relationships with industry can contribute to the advancement of medical research and the development of life-saving technologies, the Institute of Medicine recommended disclosure of these relationships because they also "present the risk of undue influence on professional judgments" and thereby "may jeopardize the integrity of scientific investigations, the objectivity of medical education, the quality of patient care, and the public's trust in medicine."[2]

I. Rationale for Disclosure

In a 2009 nationwide survey, 83.9 percent of physicians reported having financial or other interactions with the drug, device or other medical industries, including 70.6 percent receiving food and beverages, 63.8 percent receiving drug samples, 8.6 percent participating in industry funded speaker bureaus, and 6.7 percent receiving consulting contracts.[3] These interactions reflect the substantial industry investment in marketing to physicians – drug companies alone spent $24 billion on physician marketing in 2012, including $5.7 billion for samples.[4]

In response to concerns about the impact of these extensive relationships, disclosure and transparency policies have been developed and implemented over the last two decades by the Office of the Inspector General, the Public Health Service, the U.S. Food and Drug Administration (FDA), state and federal legislators, state regulators, medical organizations, consumer and student advocates and industry trade groups. Academic medical centers (AMCs), as centers of patient care, medical education and biomedical research, have an especially critical role to play.[5] For that reason, the Association of American Medical Colleges (AAMC) recommended that all AMCs adopt policies to require disclosure of financial relationships with industry. Disclosure allows the institution to effectively and carefully manage industry relationships that are not prohibited.[6]

"Principled work with industry can facilitate valuable discoveries. However, to avoid improper bias in our work and maintain the public trust, we must be transparent about our financial relationships with industry and manage them effectively."

—Lynn Zentner, JD, Director of Institutional Compliance, University of Minnesota

II. Arguments For and Against

A few academic critics have argued that there is scant evidence that industry collaboration puts patients at risk and warn that detailed disclosures of industry relationships should not be used to "create implications of impropriety in what are perfectly legitimate interactions."[7] [8]

However, evidence from lawsuits has documented that industry inducements have skewed clinical decision making, increased the cost of health care programs for government and consumers, and increased the risk of overuse or inappropriate use of drugs and devices.[9] Studies also show that physician–industry relationships are associated with many risks, including reduced generic prescribing, prescribing patterns inconsistent with evidence-based guidelines, increased drug costs, and requests for additions to hospital formularies.[10]

Patients are also concerned about the potential for bias in their care. A recent systematic review found that "patients believe financial ties [with the pharmaceutical and device industries] influence professional behavior and should be disclosed…."[11]

A few social science experimental studies have shown evidence of unintended consequences to disclosure. One study concluded that a physician, after making a disclosure of a potential conflict of interest to a patient, might feel more justified in offering biased medical advice because the patient was warned.[12] Another study, using hypothetical patient–physician interactions, showed increased pressure on the part of the patient to comply after disclosure because of anxiety about insinuating that the physician might be corrupt. Yet overall, disclosure decreased trust in the advice of the physician, and when a third party made the disclosure, patients felt even less trust in the advice.

III. Policy Considerations

Disclosure to the institution

Since 1995, the U.S. Public Health Service (PHS) has required disclosure of an investigator's significant financial interests (SFI) related to PHS-funded research to the institution. In 2011, PHS lowered the threshold from $10,000 to $5,000 per company and began requiring disclosure of payments related to all responsibilities at the institution, not only research.[13]

Most AMCs now require disclosure not only by PHS research staff, but by other research, clinical, teaching, and key administrative staff. In its 2013 annual scorecard, the American Medical Student Association reported that 69 percent of the 158 medical schools that submitted policies now require disclosure of financial relationships to the institution. However, only 26 percent of medical schools go further, requiring public disclosure on a website or directly to patients, suggesting there is significant opportunity for policy improvement.[14]

Disclosure policies allow an institution to evaluate the potential for bias when industry relationships exist and to implement management plans in response. Plans can protect patients, students, or research integrity by ending or reducing payments; forgoing participation in decisions related to the conflict; modifying the design of research; replacing a conflicted principal investigator with someone without conflicts; or providing independent monitors for research or medical education.[15] To address clinical care, a plan could include corroboration of the relevant prescribing decisions by a nonconflicted colleague; monitoring of practice patterns by an oversight committee; and transfer of a patient to a nonconflicted colleague.[16]

Disclosure to patients, students, research participants and the public

COI policies should require disclosures to those who are most likely to be affected by potential provider bias. Taking an active step to provide this information about conflicts of interest, either directly by the conflicted provider, or by a third party, can allow or invite an important discussion of the significance of the conflict.

Patients: The AAMC recommends disclosure to patients when a potential COI is related to prescribing of particular drugs or devices.[17] The written policies below from three academic medical centers follow this recommendation. The American Academy of Orthopedic Surgeons advises that orthopedists communicate to patients all financial relationships with vendors, through handouts or posted announcements.[18]

We found no research testing specific methods of communicating COIs to patients. However, there is extensive research on communication between providers and patients in shared decision making (SDM) and informed consent.[19] For instance, studies of optimal patient communication in SDM suggest that merely providing patients with COI information through inaccessible formats, such as typical informed consent forms, would not be an acceptable solution. Randomized trials have demonstrated that carefully constructed, accessible patient decision aids, including videos, are effective at enabling patients to adequately evaluate information in order to make decisions about their care.[20] [21] SDM also places a strong emphasis on patient preferences and control, a principle that should inform communications on COI as well. For instance, it may be best for patients to receive COI information from an unbiased third party, rather than directly from their provider. Videos or a website could play a role in this process, allowing patients to think about the information and plan their response without feeling pressured.

Medical students and residents: Just as Accreditation Council for Continuing Medical Education (ACCME) requires disclosure of COIs by lecturers in a continuing medical education setting, institutions should require disclosure to all students and residents in both clinical and nonclinical educational settings. Strong transparency rules communicate the values of professionalism and help to prepare trainees to resist pressures from peers and industry that undermine evidence-based prescribing in their future medical practices.[22]

"Being a new medical school, TCMC had an opportunity to craft robust COI policies at the outset, using best practices as our foundation and a touchstone for continued policy evolution."

—Andrea K. DiMattia, MEd, Associate Dean of Faculty Affairs & Faculty Development The Commonwealth Medical College

A study of disclosure in one medical school found that, after introduction of disclosure policies, students were more critical of industry relationships. There was more support for limiting industry meetings with students and less agreement with industry funding for medical school programs.[23]

The University of Minnesota and Washington University School of Medicine (see below) both require disclosure to students when faculty financial relationships involve drugs or devices that are related to educational presentations.

Research participants: Currently, the 2011 PHS regulations require that all financial conflicts of interest (FCOIs) over $5,000 be reported on a public website or be provided upon request to research participants. Institutions should consider lowering these thresholds and require researchers to make all their COIs transparent to all research participants, regardless of the involvement of PHS funding.

Public Website: A few institutions make FCOIs of their faculty transparent on a public website. Washington University School of Medicine posts information on financial relationships for all clinical faculty members earning over $10,000 per year from industry or receiving equity from an industry relationship, stating that "[t]ransparency regarding industry relationships is an important mechanism for preserving public trust and professional integrity . . . ."

IV. Monitoring and Enforcement

Institutions should design individual management plans for staff with significant financial interests, and the institution should provide training and monitoring to ensure that these plans are followed. Institutions should also track trends in reported financial interactions and use this information to improve policies or enforcement.

A failure by faculty and staff to comply with requirements to disclose financial relationships should have serious consequences. PHS requires the institution to submit a retrospective review of potential bias in research when an investigator fails to disclose. In the realm of patient care or medical education, failure to disclose financial relationships prevents the institution from protecting patients and students by managing COIs appropriately. With the advent of public transparency under the Physician Payments Sunshine Act (PPSA), now called the Center for Medicare and Medicaid Services (CMS) CMS Open Payments, the institution's good reputation is potentially at risk as well.

Disclosure policies should be enforced like other institutional conflict of interest policies, with the option of disciplinary action, loss of patient privileges, limitations on teaching or supervision of graduate students, or even termination.

"How can students build a strong, evidence-based foundation of medical knowledge without an understanding of the influences and money behind their educators?"

—Tina Musa, second year medical student, Lake Erie College of Osteopathic Medicine.

The Physician Payment Sunshine Act: opportunities and challenges for AMCs

After years of broad-based advocacy, comprehensive public disclosure of industry payments to physicians and teaching hospitals is now required by the 2010 Patient Protection and Affordable Care Act.[24] The Physician Payments Sunshine Act rules require industry to report all payments over $10 (or all payments if they total more than $100 annually), beginning on August 1, 2013. The amount, type, and nature of these payments, along with the name of the recipient and any medical product associated with the payment must be reported to CMS and will be posted on a public, searchable "Open Payments" website beginning September 30, 2014.[25]

This data will allow compliance departments to verify internal disclosures made by their physicians. State disclosure systems in Massachusetts and Minnesota, as well as industry disclosure websites, have already been used by some institutions for this purpose.[26] Furthermore, Congressional investigators and the media have effectively used this data to expose clinicians that have accepted industry payments in violation of institutional policies.[27]

In order to strengthen enforcement of their own policies, all institutions should prepare themselves to cross-check their disclosure data with the information released on the CMS Open Payments website. Institutions should take the lead in educating their physician staff about the PPSA requirements and the rationale for them – this could be offered to voluntary faculty and admitting physicians as well. Institutions can also assist their staff in making any necessary corrections to the Open Payments data during the 45-day prior-review process. The fundamental message from the institution should be that the new requirements represent the public's expectation of transparency in these financial relationships and is consistent with the institution's own commitment to the highest quality patient care, medical education and research.

Model Policies

UNIVERSITY OF MINNESOTA INDIVIDUAL COI: STANDARDS THAT GOVERN THOSE INVOLVED IN CLINICAL CARE

All covered individuals will be held to a shared ethical standard of ensuring that their relationships with business entities are transparent, grounded in objectivity, and do not improperly influence their professional judgment, exercise of University responsibilities, or performance of University-related activities.

Covered individuals [include those] involved in one or more higher-risk activities….clinical health care; human subjects research subject involving "more than minimal risk" to subjects; technology commercialization; in a position to exert control over the content of University curriculum…; in a position to take any other action on behalf of the University that could benefit…commercial interests.

Section I. Reporting and Managing Relationships with Business Entities

Annual Reporting [required of all covered individuals, including Adjunct Faculty] (1) **Remuneration** received from one or more business entities in the calendar year preceding the Report of External Professional Activities (REPA) or anticipated during the calendar year following REPA reporting, in ranges specified on the REPA (e.g. $1 to $1,000). (2) **Equity Interests in Both Publicly Traded and Non-Publicly Traded Entities** (e.g., stock, stock options, or other ownership interest)…. (3) **All Royalties Paid in Connection with Intellectual Property Rights** such as patents and copyrights, including agreements to share in royalties related to such rights. (4)….**Business Interests** include holding any executive position in a business or membership on a board of a business entity, whether or not such activities are compensated. (5)….**Travel-related information**. Individuals engaged in PHS sponsored research must report travel paid for or reimbursed by a business entity….

Section II. Conflict of Interest Review

Thresholds for Conflict of Interest Review

REPAs will be referred to the Conflict of Interest Program for review when the individual has, annually the following [thresholds that define a Significant Financial Interest]: **Remuneration** that equals or exceeds $5,000; **Equity interests** in a publicly traded business…that equals or exceed $5,000; **Equity interests in a non-publicly traded business entity in any amount**; and….the value of any royalties….that equals or exceeds $5,000. **Business:** Holds any executive position in a business entity or membership on a board of a business entity.

SECTION III. Disclosing Business Interests and Significant Financial Interests

A. Whether or not required by the terms of a conflict management plan, covered individuals must make the following disclosures [of business interests and SFIs]:

(1) **In the context of clinical health care:** Covered individuals, who provide clinical care and who also have a business interest or a significant financial interest in a business which manufactures or distributes pharmaceuticals, medical devices, or other health care products, **must provide a written disclosure of that business or financial interest to all patients for whom the individual prescribes a branded product of that business. The same disclosure must be made when the business interest or significant financial interest is held by a family member.** The written disclosure may be made in the form of a letter addressed to the individual patient or, alternatively, in the form of a declaration which adequately discloses the financial interest but may not be individually addressed to each patient. In either case, documentation of the disclosure must be made in the health record.

(2) **To research sponsors:** Covered individuals must disclose relevant business or significant financial interests to sponsors of research as required by the sponsor.

(3) **To professional journals and other publications…**

(4) **In the context of a public appearance:** Covered individuals must

disclose relevant business or significant financial interests when making an appearance, either in person or by way of a written communication, before any public body, commission, group, or individual, to present facts or to give an opinion respecting any issue or matter up for consideration, discussion, or action.

(5) **When serving on vendor selection committees…**

B. Public Disclosure of Financial and Business Interests

When responding to external requests for financial conflict of interest information associated with PHS-funded research: The University will provide the following information in a written response within five business days of the request: (a) the investigator's name, title, and role on the research; (b) the name of the business entity in which the SFI is held; (c) the nature of the SFI; and (d) the approximate value of the SFI in dollar ranges or a statement that the value cannot be readily determined.

Section IV. Compliance

Non-compliance may result in disciplinary action, up to and including termination of employment, as well as ineligibility of covered individuals to submit grant applications, seek approval from the Human Research Protection Program, or supervise graduate students. Non-compliance may also result in other adverse action by UMP or Fairview. For individuals engaged in PHS-sponsored research, failure to timely disclose a significant financial interest may result in a retrospective review to determine whether any PHS-funded research or portion of the research, conducted during the period of noncompliance, was biased.

http://policy.umn.edu/Policies/Operations/Compliance/CLINICALCOI.html

WASHINGTON UNIVERSITY SCHOOL OF MEDICINE PHARMACEUTICAL AND MEDICAL DEVICE INDUSTRY POLICY

I. Purpose

The Washington University School of Medicine and its physicians and health professionals recognize that the best interest of the patient is paramount and acknowledge their commitment to altruism, scientific integrity and the absence of bias in medical decision making…

II. Policy

…However, Washington University and its physicians and health professionals acknowledge that these relationships [with Commercial Health Care Companies] must also be carefully scrutinized to avoid improper inducements, whether real or perceived, and that patients be advised of these relationships where that information is pertinent to informed consent.

III. University Disclosure

Washington University physicians and health professionals who engage in clinical care will disclose [all] their Financial Relationships with Commercial Health Care Companies to the University on an annual basis, and will update their disclosures immediately upon entering a new or revised Financial Relationship.

IV. Patient Disclosure
If a Washington University physician or health professional has a material Financial Relationship with a Commercial Health Care Company that manufactures permanently implantable medical devices, the physician or health professional must disclose to his/her patients this Financial Relationship before obtaining the patient's consent to utilize the device in that patient. Such disclosure shall be documented in the patient's medical record. Other material Financial Relationships with Commercial Companies may also warrant patient disclosure before a Washington University physician or health professional recommends, prescribes or uses that company's medical device, pharmaceutical or medical care related product in his/her patients.

V. Public Disclosure
Transparency regarding industry relationships is an important mechanism for preserving public trust and professional integrity. Accordingly, the following information will be posted on the WUSM Faculty Practice Plan web site for faculty members earning >$10,000 per year or receiving equity from an industry relationship: (a) Name of company… (b) Basis for payments (ex: consulting, educational lectures, royalties, equity or stock options, etc)… (c) Range of reimbursement…

VI. Industry-Supported Educational Lectures
…All financial support by industry must be reported to, and fully disclosed by, the meeting sponsor.

VII. Implementation and Enforcement
The Associate Vice Chancellor for Clinical Affairs will review faculty disclosures and manage and resolve potential clinical conflicts of interest in conjunction with the appropriate Department Chair or Program Director. The Associate Vice Chancellor for Clinical Affairs, in consultation with the Dean and the Office of the Executive Vice Chancellor and General Counsel, will **determine the thresholds for management of potential conflicts of interest, as well as the management strategies to be employed by the University…**

VIII. Remedial Action
If after thirty (30) days, the conflict of interest has not been resolved in accordance with the foregoing, the University may:
1. Suspend the faculty member's clinical privileges
2. Withdraw professional liability insurance coverage for the faculty member
3. Reduce the faculty member's salary or bonus, and/or
4. Take other actions as deemed appropriate.

https://fpp.wusm.wustl.edu/fpppolicies/Pages/ConflictofInterestClinical.aspx

Research Conflict of Interest Policy
All personal financial interests must be disclosed to the University. Determinations of Material Financial Interest for purposes of reporting to PHS-funded research follows PHS threshold of $5000. For non-PHS (e.g. NSF, industry, etc.) research, the threshold is $10,000. Public reporting is upon written request.

http://research.wustl.edu/ComplianceAreas/COI/Policy/Pages/default.aspx#preamble

THE COMMONWEALTH MEDICAL COLLEGE DISCLOSURE POLICIES

Student, Faculty and Administration: Policy on Conflicts of Interest and Interactions with Industry

The Commonwealth Medical College has a mission to educate physicians and scientists to serve society using a community-based, patient-centered, Interprofessional and evidence-based model of education that is committed to inclusion promotes discovery and utilizes innovative techniques. These goals require that faculty, students, trainees, and staff of TCMC and physicians and other TCMC employees at all regional locations interact with representatives of the pharmaceutical, biotechnology, medical device, and hospital equipment supply industry (hereinafter Industry), in a manner that advances the use of the best available evidence so that medical advancements and new technologies become broadly and appropriately used. While the interaction with Industry can be beneficial, Industry influence can also result in unacceptable conflicts of interest that may lead to increased costs of healthcare, compromise of patient safety, negative socialization of students and trainees, bias of research results, and diminished confidence and respect among patients, the general public and regulatory officials. Because provision of financial support or gifts may exert an impact on recipients behavior, TCMC has adopted the following policy to govern the interactions between Industry and TCMC personnel….

(1-9: Specific policies listed prohibit or strictly limit industry support for CME, off-campus meetings, gifts & meals, consulting (see below), speakers, scholarships & fellowships and samples. COI curriculum is also required at orientation and each year.)

10. Policy Enforcement:
TCMC faculty and staff will disclose all ties to industry and/or disclose such relationships to patients when such a relationship might represent an apparent conflict of interest on an annual basis, using the TCMC Conflict of Interest disclosure form. This information will be included on the faculty information pages on the TCMC website.

Faculty and Staff: …Possible consequences of policy violation include but are not limited to: counseling, training, privilege reduction or revocation, requiring repayment of monies acquired in violation of policies, fines or termination. Industry personnel: Any violations of this policy may be subject to any of the following disciplinary actions: Warnings issued to corporation and supervisory personnel (written &/or verbal); Access to TCMC and business privileges revoked for offending representative and other company personnel; Lengthy restriction by all personnel from any access to the property for varying lengths

http://www.thecommonwealthmedical.com/oth/Page.asp?PageID=OTH000456

CME Disclosure Policy:

Speaker/Planner Disclosure

…This policy requires disclosure of all financial relationships between a speaker/planner and the commercial supporter (if applicable) or with the manufacturer of any product or class of products they plan to discuss in an educational activity sponsored by TCMC. This policy is designed to provide the audience with an opportunity to review any affiliations between a speaker/planner and supporting organization(s) for the purpose of determining the potential presences of bias or influence over educational content…

http://www.tcmedc.net/policy_db/action/policy_output.php?id=2786

Research Disclosure Policy:

…Any faculty member or administrative staff member with a potential or actual conflict of interest in relation to a sponsored programs, sub-award or consulting agreement on a sponsored program, or who participates or anticipates such participation in outside activities where such conflicts of interests may rise shall disclose in writing such concerns or activities to their immediate supervisor. This report must be submitted for review at the earlier of: (1) prior to submission of the proposal to the outside vendor or participation with an outside vendor; or (2) as soon as the conflict of interest arises. If the conflict of interest arises after submission of proposal or participation in an outside activity, the faculty member or administrative staff may not participate or begin in project work until the conflict of interest has been resolved. For the purposes of this policy, a conflict of interest exists when the College, through procedures described in the policy set forth by TCMC, determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of sponsored programs…

Addendum addresses specific PHS requirements.

References

1. Lo B. Serving two masters – conflicts of interest in academic medicine. *NEJM.* 2010;362(8):669-671.

2. Institute of Medicine. *Conflict of Interest in Medical Research, Education and Practice.* Washington, D.C.: The National Academies Press; 2009.

3. Campbell EG, Rao SR, DesRoches CM, et al. Physician professionalism and changes in physician-industry relationships from 2004 to 2009. *Arch Intern Med.* 2010;170 (20):1820-1827.

4. Pew Charitable Trusts Prescription Project. Persuading the prescribers: Pharmaceutical industry marketing and its influence on physicians and patients. November 11, 2013. http://www.pewhealth.org/other-resource/persuading-the-prescribers-pharmaceutical-industry-marketing-and-its-influence-on-physicians-and-patients-85899439814. Accessed January 22, 2014.

5. Brennan TA, Rothman DJ, Blank L, et al. Health industry practices that create conflicts of interest. *JAMA.* 2006;295(4):429-433.

6. Association of American Medical Colleges. *Industry Funding of Medical Education. Report of a AAMC Task Force.* Washington, D.C.;2008.

7. Weber MA, Black HR, Fonseca R, et al. Association of clinical researchers and educators a statement on relationships between physicians and industry. *Endocrine Practice.* 2012;18(6):1029-1037.

8. Stossel T. Who paid for your doctor's bagel? ObamaCare's 'Sunshine Act' will benefit only accountants, bureaucrats and lawyers. *Wall Street Journal.* January 23, 2012. http://online.wsj.com/news/articles/SB10001424052970204680045771668407607480000. Accessed January 22, 2014.

9. Almashat S, Preston C, Waterman T, Wolfe S. *Rapidly Increasing Criminal and Civil Monetary Penalties Against the Pharmaceutical Industry: 1991 to 2010.* Washington D.C.: Public Citizen's Health Research Group; December 16, 2010. http://www.citizen.org/documents/rapidlyincreasingcriminalandcivilpenalties.pdf. Accessed January 23, 2014.

10. Institute of Medicine. *Conflict of Interest in Medical Research, Education and Practice.* Washington, D.C.: The National Academies Press; 2009.

11. Licurse A, Barber E, Joffe S, Gross, C. The impact of disclosing financial ties in research and clinical care: A systematic review. *Arch Intern Med.* 2010;170(8):675-682.

12. Loewenstein G, Sah S, Cain DM. The unintended consequences of conflict of interest disclosure. *JAMA*. 2012;307(7):669-670.

13. Department of Health and Human Services. Rules and regulations. *Federal Register.* August 25, 2011. http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf. Accessed January 23, 2014.

14. American Medical Student Association. AMSA scorecard. http://www.amsascorecard.org/. Accessed January 23, 2014.

15. Institute of Medicine. *Conflict of Interest in Medical Research, Education and Practice.* Washington, D.C.: The National Academies Press; April 2009:119.

16. Mayo Clinic. Conflict of interest policy. December 2013. http://www.mayo.edu/pmts/mc0200-mc0299/mc0219-09.pdf. Accessed January 23, 2014.

17. Association of American Medical Colleges. *Recommendations for Physician Financial Relationships in Clinical Decision Making: Report of the Task Force on Financial Conflicts of Interest in Clinical Care.* Washington, D.C.; 2010: 10.

18. Pew Charitable Trusts, Pew Prescription Project and the Expert Task Force on Conflict of Interest in Medicine. Recommendations for best practices. http://www.pewhealth.org/uploadedFiles/PHG/Content_Level_Pages/Reports/COI-Best-Practices-Report.pdf Accessed January 10, 2014.

19. Lee EO, Emanuel EJ. Shared decision making to improve care and reduce costs. *NEJM.* 2013;368(1):6-8

20. Stacey D, Bennett CL, Barry MJ, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev.* 2011;10(10):1-208. CD001431.

21. Volandes AE. Randomized controlled trial of a video decision support tool for cardiopulmonary resuscitation decision making in advanced cancer. *JCO.* 2013;31(3):380-386.

22. Austed K, Kesselheim A. Medical students' exposure to and attitudes about the pharmaceutical industry: A systematic review. *PLoS Medicine.* 2011;8(5):1-12.

23. Kim A, Mumm LA, Korenstein D. Routine conflict of interest disclosure by preclinical lecturers and medical students' attitudes toward the pharmaceutical and device industries. *JAMA.* 2012; 308(21):2187-2189.

24. Center for Medicare and Medicaid Services. Open Payments. October 21, 2013. http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-payment-Transparency-Program/index.html. Accessed January 27, 2014.

25. Agrawal SA, Brennan N, Budetti P. The Sunshine Act – effects on physicians. *NEJM.* 2013;368(22):2054-2057.

26. Zentner, L. Personal communication, September 9, 2013; Randolph J. Personal communication, May 18, 2012; Holcombe J. Personal communication, October19, 2013.

27. Sagana E, Orenstein C, Weber T, Jones R, Merrill J. Dollars for docs: How industry dollars reach your doctors. ProPublica. http://projects.propublica.org/docdollars/. Accessed January 27, 2014.

Authors

Marcia Hams, MA
Program Director, Prescription Access and Quality, Community Catalyst

Stephen R. Smith, MD, MPH
Professor Emeritus of Family Medicine
Warren Alpert Medical School of Brown University

Wells Wilkinson, JD
Senior Policy Analyst, Community Catalyst

This Toolkit is one of a series in Community Catalyst's Policy Guide for Academic Medical Centers and Medical Schools, available online at:

http://tinyurl.com/AmcModelCoiPolicy

The Toolkit is a publication of Community Catalyst, a national, nonprofit consumer advocacy organization dedicated to making quality affordable health care accessible to everyone. Among its prescription drug initiatives, Community Catalyst combats pharmaceutical marketing that creates conflicts-of-interest and threatens the safety and quality of patient care. We provide strategic assistance to medical schools and teaching hospitals seeking to improve their conflict-of-interest policies as part of the Partnership to Advance Conflict-Free Medical Education (PACME), a collaboration of Community Catalyst, The Pew Charitable Trusts, the American Medical Student Association and the National Physicians Alliance. PACME is supported by a grant from the Attorney General Consumer and Prescriber Grant Program, which was funded by the multi-state settlement of consumer fraud claims regarding the marketing of the prescription drug Neurontin.