

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



Toolkit on COI Policy Implementation

COI Policy Implementation

Community Catalyst has produced a number of toolkits designed to help medical schools and academic medical centers (AMCs) create or strengthen policies on conflict of interest (COI) related to relationships with the pharmaceutical and medical device industries. These toolkits (available at <http://tinyurl.com/AmcModelCoiPolicy>) provide the rationale, supporting evidence, policy considerations, and model policies from other institutions on each of nine policy domains. In contrast, the following resource sets aside issues about specific policies and provides a guide to the process of COI policy development and implementation.

Faculty and staff who are interested in helping to expand or improve COI policies in their institution will find this toolkit helpful. This resource draws upon articles in the academic literature^{1,2} as well as expert opinions of leaders at many institutions who have successfully shepherded COI policy initiatives at their own institutions.

The focus of this implementation guide is on voluntary actions that the institution can take to define appropriate relationships of individuals with industry. Mandatory rules and regulations set by the Public Health Service that govern research are not discussed here. In addition, while institutional conflicts of interest are important, this topic is beyond the scope of this toolkit, though many of the recommendations are equally applicable when applied to institutions rather than individuals.

No single strategy or formula will be right for every institution. Modification will be required depending on local circumstances. Nevertheless, the recommendations presented reflect a broad consensus of opinion that will be found generally applicable across institutions.

I. Professionalism and the Public Good as the Central Tenets

Professionalism must be the central tenet driving COI policy development. As discussed in a paper by Rothman, professionalism includes putting the patient's interest above the physician's financial interests.³ Thus, the argument as to why COI policies are needed must focus on serving the interests of the patients and the public good. Once the issue is framed in this way, then the discussion becomes one of how best to accomplish it, not whether to accomplish it.

“Successful development and implementation of COI policies is greatly enhanced by a consistent appeal to the principles of medical professionalism, a unifying framework for members of the academic community with diverse opinions on COI.”

*— David Coleman, MD
Director, Department of Medicine,
Boston University
School of Medicine*

Avoid creating the perception that COI is about whether someone is a good or bad person based on the existence of a conflict of interest. Instead, focus on the need to articulate rules and expectations that will enhance the trustworthiness of faculty and clinicians, and thereby ensure public trust in the medical profession. Impress on faculty that such policies are valuable because even the appearance of a conflict of interest can undermine trust.

Not all conflicts of interest can be totally avoided or eliminated, but they can be managed appropriately to mitigate the dangers. And the dangers inherent in a conflict of interest will vary from slight to very serious, as when the health and safety of patients are concerned. Mitigation plans must take into account those variations.

Convince faculty of the importance of serving as good role models for their students and residents. Promote the idea that adhering to COI policies in their practices provides the best educational environment by demonstrating the highest levels of professionalism and critical thinking.

Don't avoid responsibility by making industry the scapegoat. While industry should be constrained by legal and ethical standards, for-profit companies can be expected to act in ways that increase their sales and profits. Instead, focus on the responsibility of the medical profession to safeguard its own integrity by placing the interests of patients and society first and eschewing practices that might compromise or even appear to compromise their position of trust.

II. Good Process is the Key to Success

The process of achieving policy change can be slow and arduous. Success might require persistence and commitment over an extended period of time—months and years, not days and weeks. A clear strategy with a plan of action and benchmarks of progress must be laid out at the beginning. The plan of action must delineate who the key audiences are, how they will be approached and in what order, what methods of communication will be used and to whom, and a timetable.

A team that includes both physicians and non-physicians leading the effort will ensure the best access to both the medical staff and the “C-suite” staff. Ideally, this might include the chief medical officer, the institution's compliance officer, and an associate dean of the medical school.

The process must be inclusive and transparent. Identify and include all the key stakeholder groups including the full-time medical faculty, clinical voluntary faculty, basic science faculty, nursing and pharmacy staff, executive and business staff, general counsel, students and house staff, and, if applicable, representatives from schools for other health professions, such as nursing and dentistry. Consideration should be given to contacting local representatives of pharmaceutical and medical device companies with close relationships to the institution, both to provide them with the courtesy of informing them of the effort and to elicit their perspective on the issues.

“Faculty involvement is paramount to successful implementation. Since we are asking for greater transparency from faculty, the institution should be transparent about the goals, interests, and rationale behind new policy initiatives.”

*—Toby Boenig, JD
Vice President and Chief Compliance Officer, University of Texas Medical Branch*

Provide information on the reasons for the proposed policy changes to the stakeholder groups repeatedly and through multiple means, especially through face-to-face meetings that allow dialogue. Listen respectfully to those who oppose the changes. Try to understand the reasons for their opposition—it may be different than what you assumed and accommodations might be possible. There may be subtle nuances that are the key to compromise. Acknowledge your understanding of their reasons for being against the change. While using this approach may not change their minds, it may get you to the point where they will agree to express their opposition privately, but not oppose the changes publicly.

Keep the process moving forward. If insurmountable obstacles are encountered (e.g., one of the other health professional schools cannot agree to the proposed policy), then try to circumvent them (e.g., don't include that health professional school) or compromise on one facet of the proposed policy change while moving forward with the rest. Be flexible—rigidity can doom your progress.

III. Focus on Broad Principles First, Details Later

Use an iterative process for your plan of action. Start by getting agreement on broad, general principles (e.g., gifts from industry should be prohibited). Save the details for later.

Consider using a survey to assess opinion on these general principles once some progress has been made, then feed the results back to the constituencies. When individuals who are on the fence see that the majority of their peers support the policy initiative, they are likely to get on board themselves.

IV. Enlist Key Leaders

Having the endorsement of key leaders such as the dean, chancellor, CEO, and president is essential at the outset. The more far-reaching and controversial the policy change, the more essential is their enlistment.

If a key leader voices opposition, then the process should stop there and ways to get that leader on board or at least agree not to actively oppose the initiative should be devised. A well-respected outside authority might be invited in to talk with the recalcitrant leader about why the change is important. Another influential person within the institution, such as a department chair, who supports the policy change could be asked to speak to the leader who is opposed.

After the key leaders have indicated their support, a subcommittee of department chairs might be empanelled to draft specific language for the policy change. The subcommittee would submit their recommendations to all the other department chairs. Once endorsed by the department chairs, the policy could be brought to the general faculty.

The Office of the General Counsel should be involved in the drafting process to assure the right language is used and important contingencies have been considered.

In some cases, pressure from other sources may prove valuable in moving institutional leaders to act or in supporting them in overcoming internal opposition to change. Medical students can be a potent force for change. Those who are leading the change process should reach out to medical students through their student government or organizations like the local chapter of the American Medical Student Association (AMSA) to inform them of the issues and to recruit volunteers. Residents and fellows should also be informed of the issues since policy changes may have a direct bearing on them (e.g., restricting industry support for fellowships or travel to educational meetings). Ideally, residents and fellows should have input into the policy-change process and endorse the recommendations. At the very least, the information they have should be accurate and their concerns acknowledged.

V. Disseminate Draft Policies Widely

The draft policy changes should be disseminated widely to all constituencies who would be affected. Meetings should be held with key individuals and groups to explain the policy, answer questions, and solicit feedback.

Leaders can cite the Physician Payments Sunshine Act (PPSA) Open Payments⁴ as an example of the public's demand for greater transparency and the need to be comfortable with the nature of one's relationships with industry. Use this to explain the rationale for the new policy initiative, but avoid using PPSA as a way of frightening or threatening the faculty.

Enlist medical students and residents to spread the word among their constituencies and to mobilize support for the policy change.

Be ready to answer questions about the impact the policy change will have on resources. Given the financial realities, having institutional funds to replace industry funding will be very limited, if present at all. Use whatever available institutional resources in the most strategic way possible (e.g., providing drugs for indigent patients in place of samples). Most importantly, don't promise something that can't be delivered.

VI. Provide Alternative Sources of Information and Education

Those opposed to more restrictive relationships with industry will argue that the policies will reduce the information on new drugs and medical devices available to clinicians. Plan to provide alternative sources of information as a counter to this argument. Clinical pharmacists can be an independent, unbiased source of information about new drugs, new indications for existing drugs, adverse event warnings, cost information, therapeutic comparisons, and alternative treatments. This information

“Passionate for patient care and hungry for clinical experience, medical students are natural allies and stakeholders in COI policy development and implementation. Don't neglect the perspective and support of tomorrow's doctors.”

*— Teddy Fagrelus,
Medical Student, University
of Minnesota and Just
Medicine Fellow, American
Medical Student Association*

can be shared through online newsletters, emails, departmental presentations, or one-on-one meetings. Clinical pharmacists should be made available for formal consultations at the request of prescribers.

Prescribers on staff should also be provided with immediate access to online resources that can provide objective information on drugs such as *The Medical Letter*, *Therapeutic Guidelines*, *Prescrire* (in English), and the *BMJ Drugs and Therapeutics Bulletin*.

Relying less on industry funding may provide opportunities for enhancing local resources. Some AMC's have found that using their own faculty for continuing medical education enabled them to showcase local talent and help those faculty in the reappointment and promotion process, while reducing costs at the same time.

VII. Nurture Appropriate Relationships with Industry

Emphasize that COI policy initiatives are not a campaign against pharmaceutical companies by nurturing appropriate relationships with industry such as bona fide research collaborations, consulting agreements, and teaching (e.g., medical school faculty teaching new developments in the basic sciences to the scientists at pharmaceutical companies). Work with pharmaceutical companies in finding appropriate ways to make drugs available to indigent patients such as through a central pharmacy.

Acknowledge that maintaining appropriate relationships and assuring professional behavior is a joint responsibility of both medicine and industry. Both the medical profession and industry are dedicated to improving the health of the population. Deviations from those expected standards of behavior have occurred on both sides. It is in the best interest of industry, medicine, and the public that problematic conflicts of interest be avoided whenever possible and when unavoidable, managed appropriately.

Recognize the challenges that are being experienced both by the pharmaceutical industry and the practice of medicine in today's world. These stresses can be best managed in an atmosphere of mutual understanding and respect.

VIII. Trust but Verify

Most physicians adhere to the highest standards of professionalism, but a small percentage does not. Therefore, mechanisms must be put in place to verify adherence to COI policies. Faculty and staff must regularly report their *financial interests* so that the institution can decide whether these practices could create or indicate a potential conflict of interest. Avoid asking the people themselves whether they have any conflicts of interest to report. The institution needs to make that determination.

Now that mandatory disclosures by industry are required through PPSA, opportunities exist to go into the database and find out who's getting the

money, but the institution needs to devote the necessary human resources to find this out and pursue any discrepancies with institutional disclosure or prohibitions.

Clear processes must be delineated describing how violations of the policies will be adjudicated and the range of penalties that can be applied. See the section on model policies below for examples.

IX. New Medical Schools

The above principles apply equally to new medical schools, but a few unique characteristics of new medical schools deserve special attention. Since new schools usually don't have a full complement of faculty during the process of initial accreditation, administrative staff will, by necessity, need to take the lead in development of COI policies. Once the school is fully accredited and faculty and students recruited, the policies can be reviewed by these wider constituencies and modified, if needed.

New schools should seek out best practices as cited by the Association of American Medical Colleges,⁵ the Institute of Medicine,⁶ the AMSA Scorecard,⁷ and the Partnership to Advance Conflict Free Medical Education⁸ and adopt those as their initial set of policies. Typically, new schools are more flexible and open-minded than their well-established counterparts and can take a leading role in managing their relationships with industry in the most professional manner.

While volunteer, community-based faculty who are recruited by new medical schools may be used to relating to industry in ways that harken back to older times, they can be convinced to adopt the new standards of the medical school by appealing to their desire to be the best teachers they can be for their students. The importance of serving as good role models should be emphasized.

Conclusion

Implementing policy change is never easy. As Machiavelli wrote: "There is nothing more difficult to take in hand, more perilous to conduct, or more uncertain in its success, than to take the lead in the introduction of a new order of things." (*The Prince* [1532]) Despite this warning, taking the lead in promulgating robust COI policies is well worth the effort. At stake are the public's health and the very heart and soul of medicine as a profession.

Leaders with courage, persistence, and fortitude are required. Be flexible and be ready to compromise, but maintain a strategic vision.

Seek allies within the institution and without. Appeal to the noblest aims of medicine.

You are part of a broad effort to achieve crucial cultural change.

Model Policies

UMASSMEMORIAL VENDOR RELATIONS POLICY

Enforcement

Department chairs and senior managers are expected to enforce this policy with the support of the Compliance Office and Medical Staff Executive Committee. Alleged violations of this policy should be communicated to the respective department chair or senior manager or to the Compliance Office. The Compliance Office will work with the respective department chair or senior manager to determine appropriate follow up. It is the intent of the organization, when practical and feasible, to emphasize education and assistance to facilitate compliance and clarification of expectations. However, the organization reserves the right to impose appropriate discipline when warranted under the circumstances particularly in cases of intentional, egregious or repetitive non-compliance. Appropriate corrective action will be determined by the department chair or senior manager in concert with the Chief Medical Officer and Chief Compliance Officer. Vendors who violate this policy will be subject to disciplinary action.

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Alleged violations of this policy shall be investigated by the TUSM Office of the Dean or Vice Dean for Academic and Clinical Affairs or the Vice Dean for Research. When indicated, such alleged violations of this policy shall be referred to the individual's dean and department chair or to the individual's immediate supervisor who shall, in conjunction with the Office of the Vice Dean determine what actions, if any, shall be taken. Such action may depend upon the seriousness of the violation, whether it is a first or repeat offense, and whether the violator knowingly violated the policy.

Industry representatives who are found to violate this Policy or trespass on TUSM property will be escorted away from the premises. Other appropriate sanctions will be taken, as necessary, and their industry principals will be notified.

References

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8. Pew Charitable Trusts, Pew Prescription Project, and the Expert Task Force on Conflicts of Interest in Medicine. Conflict-of-Interest policies of academic medical centers: recommendations for best practices; 2013. http://www.pewhealth.org/uploadedFiles/PHG/Content_Level_Pages/Reports/COI-Best-Practices-Report.pdf. Accessed January 10, 2014.

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This COI Toolkit is one of a series in Community Catalyst's Conflict of Interest 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.